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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

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October 25, 2016
8:30 a.m.

Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, MD 20879

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M E E T I N G

(8:30 a.m.)

DR. LOTZ: Good morning, everyone. I'd like to call this meeting to order of the Technical Electronic Product Radiation Safety Standards Committee.

I'm Dr. William Lotz, also known by my middle name, to those who have known me for years, as Greg. And I'm Chair of the Panel. I am, just a few months ago, retired from a career in the Public Health Service, working for the National Institute for Occupational Safety and Health, most recently as one of their Division Directors, the Division of Applied Research and Technology. My background is in radiofrequency and ELF bioeffects and exposure assessment, with degrees in physiology and biophysics. I have no professional organizational affiliation at this point. I'm serving simply as a retired individual.

I note for the record that the voting members present constitute a quorum as required by 21 C.F.R. Part 14.

For today's agenda, the Committee will discuss and make recommendations regarding possible FDA performance standards for the following topics: radiofrequency or RF radiation products, such as microwave ovens and wireless power transfer; laser products, including an update to amendments to the laser rule, light detection and ranging, also known as LiDAR, laser data, light fidelity (Li-Fi), energy transfer, illumination applications, and infrared applications; sunlamp products, including an update on the performance standards amendments; noncoherent light sources such as LEDs and UVC lamps, including new initiatives

Tomorrow, on October 26th, 2016, the Committee will discuss and make recommendations regarding possible FDA performance standards for the following topics: International Electrotechnical Commission, or IEC, standards versus performance standards for medical devices; computed tomography (CT); radiography and fluoroscopy; diagnostic and therapeutic ultrasound; and radiation therapy

Before we begin, I would like to ask our distinguished Panel members and FDA staff seated at this table to introduce themselves. Please state your name, your area of expertise, your position, and your affiliation. And I'll begin to my right with Dr. Lambeth.

DR. LAMBETH: Good morning. As noted, my name is David Lambeth. I'm now an emeritus faculty member of Carnegie Mellon University. My background is in educational electrical engineering, followed by a Ph.D. in physics. I've worked on many things over many years. Primarily at the university, my research area was in materials and sensors and devices, but I worked on RF systems, laser systems, and too many things to actually mention over the years. But I've been on the Committee once before, but not for several years. So this is sort of a return trip, but it's been long enough that I'm probably considered a newbie.

DR. McCOLLOUGH: Good morning. My name is Cynthia McCollough. I am a Professor of Medical Physics and Biomedical Engineering at the Mayo Clinic College of Medicine in Rochester, Minnesota. My background is in medical physics, and I have a degree, a master's and Ph.D., in medical physics. My area of expertise surrounds primarily CT imaging, but radiation protection also in general.

MR. KEITH: I'm Larry Keith, otherwise known as Sam, like Greg is, by my middle name. I am a Senior Health Physicist at the Centers for Disease Control and Prevention in the Division of Toxicology and Human Health Sciences. My background is in chemical engineering, followed by medical and environmental health physics, and I've worked for the Department of the Navy, EPA, and CDC, a stint at Emory University, and my focus is on radionuclide toxicology. And for those who know me well, my wife passed of cancer, and so I've had an opportunity over about 3 years to learn how to try to interpret CT imaging and PET imaging, and so I've gained quite an insight and an interest in the field.

DR. IRWIN: Good morning. My name is Bill Irwin. I'm the Radiation Control Program

Director for the State of Vermont.  I am a certified health physicist, and I have degrees in radiological physics and work environment engineering.  My doctoral dissertation was in radiofrequency radiation effects from cellular telephones.  I was, previous to my work at the State of Vermont, a radiation safety officer and health physicist at MIT and Harvard, where I worked extensively with a wide variety of devices in the electromagnetic spectrum.

Thank you.

DR. OCHS:  Hello, I'm Robert Ochs.  I'm the Director for the Division of Radiological Health at FDA.  My background is in biomedical physics, and my primary experience for the past couple years has been in diagnostic imaging.

DR. MILLER:  Good morning.  My name is Donald Miller, and I'm the Chief Medical Officer for Radiological Health at the Center for Devices and Radiological Health.  I am by training an interventional radiologist, and I was in practice for 30 years before joining FDA, and my expertise and interest is in radiation protection in medicine.

DR. STEIN:  Hi, my name is Antoinette Stein, and I have a Ph.D. in environmental engineering, and my expertise is also in process control and material science, and I worked for 7-plus years at General Electric Company, in medical systems, working on their, too, designs as well as in aircraft engines, working on coating development, including physical vapor deposition, thermal spray, electropolish, and other electric methods.  I have several patents.  I also served for the State of California in their public health department, in indoor air quality, and chaired the Collaborative for High Performance Schools' Indoor Environmental Quality Committee since 2006, in which we have recommended and written best practices for green buildings.

MR. MURPHY:  I'm Patrick Murphy.  I'm the Executive Director of the International Laser Display Association.  My background and interest in safety is in visible continuous-wave lasers.  I'm also a member of the ANSI Z136.1, .6, and .10 committees.

MR. SAVIC: My name is Stanley Savic. I have a master's degree in physics. I have worked at the Argonne Cancer Research Hospital way back under the Atomic Energy Commission contract, and then at the University of Chicago Radiology Department as a medical physicist. Subsequent to that, I went to Zenith Electronics Corporation, and after I had retired from there, I devoted my time to my own consulting company, Stanley D. Savic Consulting, LLC. And my background is in medical physics, primarily in X-radiation, but I deal with other safety aspects of products that emit radiation, such as lasers and microwaves.

DR. FARAONE: Good morning. My name is Antonio Faraone. I am the Chief EME Scientist for Motorola Solutions. EME stands for electromagnetic energy. I have a Ph.D. in electrical engineering. My fields of expertise are antenna technologies, RF circuits, radiofrequency dosimetry, product compliance from an EME point of view, and RF bioeffects. I am a member of the IEEE International Committee on Electromagnetic Safety.

DR. LINET: I'm Martha Linet. I am a radiation epidemiologist at the National Cancer Institute. My research focuses on cancer and other serious health effects associated with non-ionizing and ionizing radiation. My colleagues and I have published our studies on power frequency, magnetic field exposures, residential power frequency magnetic field exposures and childhood leukemia, on brain tumors and use of cell phones, and more recently I study medical radiation workers' late health effects.

MR. ALDRICH: My name is Robert Aldrich. I am a laser safety expert for the United States Department of Defense. I'm also the Chair of the American National Standard for the Safe Use of Lasers Outdoors. I have contributed to the IEC 60825 series. I work closely with the NATO laser range safety group, ICAO, SAE, and I'm also a trainer of laser safety experts within the DoD, and I've been doing this for about 25 years.

CDR ANDERSON: Good morning. My name is Commander Anderson. I am here working for the FDA, and I am an officer in the United States Public Health Service. I will be serving as the Designated Federal Officer for this meeting.

Thank you.

DR. LOTZ: Thank you, everyone. This is Dr. Lotz again.

For members of the audience, if you have not already done so, please sign the attendance sheets that are on the tables by the doors. I'm told that's where they are, at least. I don't see tables by the doors, but perhaps just outside if not inside. I see heads nodding, so just outside. But please do register your attendance.

Commander Anderson, who just introduced herself as the Designated Federal Officer for this Committee, will make some additional introductory remarks at this time.

CDR ANDERSON: Good morning again.

In accordance with the Radiation Control for Health and Safety Act of 1968, Public Law 90-602, 21 U.S.C. Section 360k(k), the Secretary of DHHS has established the Technical Electronic Product Radiation Safety Standards Committee for consultation on matters relating to technical electronic product radiation safety.

As specified by Public Law 90-602, the Committee consists of 15 members, including the Chairman, who are appointed by the Commissioner of Food and Drugs for overlapping terms of 4 years or less. Five members are selected from government agencies, including state and federal governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative for organized labor. Members must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic products, radiation, and safety standards.

The primary function of TEPRSSC is to provide advice and consultation to the Commissioner of Food and Drugs on the technical feasibility and reasonableness of performance standards for electronic products to control the emissions of electronic product radiation from such products and to review amendments to such standards before being prescribed by the Commissioner. The Committee is not requested to review individual applications of particular products of specific firms. No vote will be taken at this meeting. And I note for the record that this meeting is of particular matters of general applicability.

Public Law 90-602 and its legislative history clearly indicate that TEPRSSC members are expected to represent a very wide range of interests, with at least one-third of the Committee nominated by the regulated industry itself and appointed on the basis of their being able to represent industry-wide concerns.

Section 534 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 360k(k) specifies that TEPRSSC members are not to be considered officers or employees of the United States for any purpose. This includes for the purpose of conflict of interest determinations. Regular government employees who are members of this Committee have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 U.S.C. Section 208, their employees.

The Agency believes that public disclosure should be made a part of the public record, which identifies each member and provides their employment affiliation. Approved by delegated authority of the Commissioner of Food and Drugs, the members of the Technical Electronic Product Radiation Safety Standards Committee are:

William Lotz, Ph.D., Chairman, biophysics; David Lambeth, Ph.D., Carnegie Mellon University; Cynthia H. McCollough, Ph.D., Mayo Clinic, Rochester, Minnesota; Antoinette Stein, Ph.D., Environmental Health Trust;

Government - Robert Aldrich, B.S.E.E., Naval Surface Warfare Center; William Irwin, Sc.D., Vermont Department of Health; Martha Linet, M.D., M.P.H., National Cancer Institute, NIH; Larry Keith, M.S., Centers for Disease Control and Prevention;

Industry - Antonio Faraone, Ph.D., Motorola Solutions, Incorporated; Patrick Murphy, B.A., M.B.A., International Laser Display Association; Stanley Savic, M.S., Savic Consulting, LLC.

Thank you.  Before I turn the meeting back over to Dr. Lotz, I'd like to make a few general announcements.

Transcripts of today's meeting will be available from Free State Court Reporting, Incorporated, telephone number (410) 974-0947.

Information on purchasing videos of today's meeting can be found on the table outside the meeting room.

Handouts of today's presentations are available at the registration desk.

The press contact for today's meeting is Stephanie Caccomo.  And could you please stand up?  Thank you.

I would like to remind everybody that members of the public and the press are not permitted in the Panel area, which is the area beyond the speaker's podium.  Again, I'd like to remind everybody that members of the public and the press are not permitted in the Panel area.  I request that reporters please wait to speak to FDA officials until after the Panel meeting has concluded.

If you'd like to present during today's Open Public Hearing session and have not already registered with AnnMarie Williams, please to do so at the registration desk.

In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time you speak.

Finally, please silence your cell phones and other electronic devices at this time.

Dr. Lotz.

DR. LOTZ: We will now proceed with the first FDA presentation. Dr. Miller will now present.

I will remind public observers at this meeting, while the meeting is open for public observation, public attendees may not participate except at the specific request of myself, the Panel Chair.

Dr. Miller, you may now begin your presentation.

DR. MILLER: Thank you, Dr. Lotz.

I would like to again welcome you and to thank the members of the Committee for donating -- well, not donating, but giving us your time and your expertise, which we so desperately need and want in order to further the mission of the Agency.

I will be talking to you a little bit about the Technical Electronic Product Radiation Safety Standards Committee, or as we refer to it amongst ourselves TEPRSSC. And you will hear us use that acronym regularly over the next 2 days, a little bit about the TEPRSSC Committee and a little bit about its scope and a little bit about its history.

You will hear us, all of us presenting for FDA over the next several days, refer to or paraphrase or quote snippets of various regulations and law. Please be aware that the content of all presentations provided for this meeting are for discussion and summary purposes only. They do not describe the full extent of requirements applicable to electronic products, for which you should please see the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Subchapter J for a full list of requirements.

So a little bit about TEPRSSC, some definitions, a little history, and a very quick look at the agenda.

TEPRSSC, as has already been said, was established by the Radiation Control for Health and Safety Act of 1968, which was subsequently incorporated into the Federal Food, Drug, and Cosmetic Act, and it says that the Secretary shall establish this Committee, which he or, in this case, she shall consult before prescribing any standard under this section.  And in context, standard means a performance standard for electronic products to control the emission of electronic product radiation.

More detail is provided in the TEPRSSC charter, which says that the Committee provides advice to FDA on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products and that the Committee may recommend electronic product radiation safety standards to the Commissioner for consideration.

In addition, TEPRSSC may also make recommendations on any other matter it deems necessary or appropriate in fulfilling the purposes of the Act.  And the purpose of the Act is to protect the public health and safety from electronic product radiation.

So you may reasonably ask what exactly is electronic product radiation?  And it is defined in a regulation as any ionizing or non-ionizing electromagnetic or particulate radiation, or any sonic, infrasonic, or ultrasonic wave emitted from an electronic product as the result of the operation of an electronic circuit in such product.  It's a very broad definition.

You will also hear us talk repeatedly over the next 2 days about products and also about devices.  In this case we refer to electronic products and medical devices, both of which are clearly defined terms.

An electronic product is defined in the regulations as any manufactured or assembled product which, when in operation, contains or acts as part of an electronic circuit and emits (or in the absence of effective shielding or other controls would emit) electronic product radiation; or a component, part or accessory of such a product that emits (or in the absence of effective shielding or other controls would emit) electronic product radiation.  Again, a very broad definition.

Medical device is defined as well in the law. It's a very long, detailed definition, and so I have not put it on the slides. The full definition is in the briefing materials, and it's also available at the GPO website.

The point here is that some of the products we regulate are electronic products, things such as light-emitting diodes, LiDAR, laser pointers, and microwave ovens. FDA also regulates medical devices such as syringes, needles, catheters, and sutures, which are clearly not electronic products. They do not use electricity or have electronic components. But there are some devices that are also products or products that are also devices, things like CT scanners, linear accelerators, sunlamps, and MRI scanners. These are regulated both as electronic products and as medical devices under separate sets of regulations.

However, the purpose of this Committee is to consider only electronic products and radiation safety standards, performance standards for electronic products. So you may consider electronic products that are not devices, and you may consider electronic products that are also devices, but not medical devices that are not products. And I hope that was sufficiently complicated.

(Laughter.)

DR. MILLER: With regard to medical devices that are also electronic products, however, you will only consider the aspects related to control of the emission of electronic product radiation. So you will not consider the medical device regulations, only the electronic product regulations.

A useful acronym that we use all the time and you will hear repeatedly over the next 2 days is EPRC, which stands for electronic product radiation control.

A little bit of history now. And as I said, TEPRSSC was created by the law passed in 1968, and I did not go back to the beginning to research its history; I only went back to the end of the last century. I can tell you, from 1999 to 2003, it met annually, and it has not met since 2003 up to today. And if you look at the topics that have been discussed in the period from 1999 through 2003, you can see certain themes that run through. CT, security screening systems, and sunlamps repeatedly appear, and you will see some of that again in the next 2 days.

In 2003 specifically, which was a 1-day meeting, six amendments to the sunlamp product standard were discussed, amendments to the fluoroscopy standard were discussed, including a brief discussion of the possibility of using IEC standards instead of FDA performance standards, and also a discussion of emerging issues in radiation security systems. The first two bullets will reappear again on the agenda for this meeting.

Since 2003 we have published the fluoroscopy amendments as a final rule in 2005, published Laser Notice 50, which allowed IEC conformance in 2007. We published ultrasound guidance, proposed laser amendments, draft MRI guidance, and re-proposed sunlamp amendments as recently as last year.

With respect to electronic products that are also medical devices, we have done an extensive amount of work since the publication of the Initiative to Reduce Radiation -- it should be Unnecessary Radiation Exposure for Medical Imaging, in 2010, including in cooperation with the manufacturer of CT Dose Check. We held a public workshop on pediatric x-ray imaging in 2012. And members, particularly of the Division of Radiological Health at FDA, have been involved in extensive ongoing work with industry, national, international, professional, and other organizations.

The agenda has already been discussed. I'll just point out that Day 1 is focused on electronic products that are not medical devices, with one exception. So you'll hear about radiofrequency radiation products and laser and light products. The exception is sunlamp products, which are considered and regulated as medical devices. And Day 2 will be devoted to EPRC issues associated with electronic products that are medical devices.

And that's my presentation. Are there any questions from the Committee?

Thank you.

DR. LOTZ: Questions from Committee members?

DR. FARAONE: I would have one question. Antonio Faraone.

The definition you mentioned talks about products that emit energy. So I was wondering about products that do not emit energy but establish an electric field, for example, something related to batteries, so direct-current devices. They would not necessarily emit, they would not radiate, but they could establish a field where interaction with a person could produce currents that may induce heating, for example. So those products. I'm thinking about in the future where we're going to have rechargeable cars, which may be charged at DC current potentially. Could those fall under the umbrella under the scope of this Committee?

DR. MILLER: It's a good question. I do not know the answer. If the battery would emit electronic product radiation without shielding, then it would be considered an electronic product. If without shielding or any other controls it could not emit electronic product radiation, then probably it would not be. But I would have to refer that to the FDA lawyers to give you a definitive answer, and I can do that.

DR. FARAONE: Thank you.

MR. MURPHY: Patrick Murphy.

The slide that you had activity since 2003, that had some amendments on it, can you tell me about TEPRSSC's role in those? In other words, is TEPRSSC something nice to have? And in the earlier period up to 2003, you would have these annually to discuss the amendments. Or is it something that TEPRSSC guidance is required before certain types of amendments? Can you discuss that?

DR. MILLER: The law says -- let me go back to what it says exactly. The Secretary, meaning in this case the Secretary of HHS, shall establish this Committee, which she shall consult before prescribing any performance standard. So we cannot publish a final rule without talking to you first.

MR. MURPHY: Okay. And again to clarify the slide that you had, the activity since 2003, none of those would actually be a performance standard under the law. They're amendments or guidance, but not standards; is that correct?

DR. MILLER: The 2005 fluoroscopy standard was discussed with this Committee in 2003 before it was published as a final rule. That's the only one.

MR. MURPHY: Okay. But everything else is not a standard, then, considered under this?

DR. MILLER: Everything else has not been published as a final rule.

MR. MURPHY: Okay, thank you.

DR. LOTZ: Any other questions from the Committee?

(No response.)

DR. LOTZ: If not, I think we're -- thank you, Dr. Miller. I think we're ready to move on to our next presentations by Mr. Kassiday and Dr. Howard.

Mr. Kassiday, you may now proceed.

MR. KASSIDAY: Hi, I'm Dan Kassiday. I'm the subject matter expert on electronic product radiation control law, regulation, applicability, and that sort of thing. We're going to talk a little bit about microwave ovens, which was one of the first standards.

There we go. Okay, so the standards always have an applicability section. In this case, a microwave oven performance standard applies to ovens that are used to cook food at home or in the commercial food services, so restaurants and that sort of thing. The standard does not apply to industrial heating with microwaves.

There's the formal definition from the standard, specifications on what frequency range, etc., that is used.

So in recent years we've had a couple of issues sort of pop back up, one of which is there's a requirement in the standard for -- sorry. The performance standard covers a number of different kinds of requirements. There's a power density limit, which after delivery to a user is limited to 5 $mW/cm^2$ at 5 cm from the outside of the oven. The standard also specifies the test conditions under which that power density measurement is to be made, including a couple of different would-be failure modes if you didn't check to make sure it didn't fail in those mode kind of things. And it also specifies that there are dual safety interlocks with a monitor circuit to shut down microwave generation in the event that both fail; and of course, labels and manuals and such things.

So the first of the two topics here for microwave ovens: wire insertion hazard. It is in some cases possible to get a straight piece of insulated, or otherwise, wire or other object into a microwave energy containing space in the oven from the outside, which would allow the wire, or otherwise, metal object to act as an antenna, which theoretically then would violate the power density limit. If you could do it without violating the power density limit, it wouldn't be a violation of the standard.

There is the formal description of that in the standard. And you may know that it also requires basically a straight-ish piece of metal, you know, 180 to 170 degrees kind of thing, no contorted or twisted things, just something that's easy to insert into the oven.

Where this came from: So when the standard was first being considered, there were ovens on the market that had just wire mesh shielding with no glass, no plastic. It was just here's your oven door, there's this nice mesh you can look through, but you could also just pop a pipe cleaner right through it or something. So they thought we should put something in the standard to avoid this, and they did. And I presume, by 1975, that most of that sort of issue was gone because of the standard, and yet they still decided it was important enough to revise it and change the way it was phrased, because originally it was just "into the microwave oven cavity," i.e., the area where you cook. They revised it in '75 to say "any microwave energy containing spaces."

So one of the tests we do when we have laboratory tests for a microwave oven is to check for wire insertion. However, our laboratory procedure does not include actually making a power density limit measurement, which is potentially an enforcement issue, and the reason they don't is because it's potentially a safety issue.

So in order to be able to move forward and take enforcement actions without quite as much back and forth, we're going to do some testing in our laboratories and determine -- see if we can determine if pretty much anytime there's anything that's inserted that's at all conductive but insulated -- that's required in the standard -- it is always acting as an antenna, and it's always going to exceed power density limits, or whether it's feasible that you could do this and still meet the limit. And if the second case is true, that we're going to look to try and develop a test procedure that's safe for technicians to routinely do, so that we can have the enforcement information that yes, you definitely violated the limit. We're not just saying you can insert a piece of metal; we're saying it does violate the limit.

The second problem that we kind of -- that's kind of popped up in recent years is we've gotten an increased number of consumer complaints about microwave ovens in general. And generally these complaints come in to the Consumer Product Safety Commission, and they're forwarded to FDA, so there's a bit of a time lag there. In 2014 we had about 10 of these reports. In the last 2 years we've had about 40, and most of them involved having the oven open and appearing that maybe it is still producing microwaves, but certainly appearing that it's still on and that lights and turntables and so forth still move.

What could be happening is it could be a partial failure where one interlock is working, and it's turned off a magnetron or other microwave-generating things, but the lights, power, and fans still are on. However, there's no guarantee that these aren't emitting microwaves. Generally, apparently people are pretty cautious about that and will unplug or turn it off and get service and, you know, complaining occasionally.

And without doing a power density measurement, we don't know if those faulty ovens are simply faulty ovens, and it's disappointing but still compliant with the standard, or they're faulty ovens and, egads, someone could get burned.

So we generally have had trouble getting these ovens in recent years. By the time we're checking back with the individual, the partially working ovens may be no longer functioning at all, or it's been disposed of by the consumer, or also frequently the oven was replaced by service, and the service guy took it away and disposed of it.

So as I mentioned, the safety interlock requirement includes a requirement for two separate interlocks to shut down microwave generation and a monitor circuit to assure that if both interlocks fail, microwave generation can no longer occur.

So obviously if they're operating with the door open and they're emitting microwaves, it's dangerous; you could get burned. Probably more likely, although again we don't have any data to confirm it, if it appears that microwave radiation could be produced, it's still causing significant anxiety and fear and stress in people, which leads at least some of them to be reporting these incidents.

So we're considering, I mean -- well, what we'll do, we're going to continue to investigate as we can. We're going to measure them when we can get a hold of them or get to them. We're considering either revising the standard, issuing guidance possibly, or working with consensus standards working groups to address the issue to make it more unambiguous. So potential -- you know, this is real early thinking. Potential thoughts are add a performance requirement which will unambiguously display when microwave generation is possible, or alternatively, make sure that all functions that make it appear that microwave function would be possible are also shut off and microwave function is not possible.

And here we are at the end. So regarding the wire insertion, is there anything else we should be looking at as far as doing -- for dealing with wire insertion test failures? Is this something we should -- well, we're moving forward on doing some testing and so forth, but is there anything else we should do really? If you have any comments on those intended actions, please provide them.

And do you recommend making any changes to the performance standard, which would be a mandatory change, and it could take quite awhile, working with consensus standards, hopefully a faster thing, or simply issuing some sort of guidance to encourage other manufacturers to make this unambiguous about the open door operation?

Thank you so much.

DR. LOTZ: Thank you, Mr. Kassiday.

Let's have a brief opportunity for the Panel to ask clarifying questions. We'll have an opportunity for more extended discussion later.

Dr. Irwin.

DR. IRWIN: Yes, thank you.

These are just clarifying questions. So the first is relative to your Slide No. 6, specifically the Title 21 C.F.R. paragraph Subsection 1030. Why is it that the wire is insulated? Couldn't someone put in a non-insulated wire while it was not operating, then turn it on?

MR. KASSIDAY: I suspect that's a safety thing for doing the test, but honestly, I do not know.

DR. IRWIN: Right.

MR. KASSIDAY: And our current expert on microwave ovens is actually out on maternity leave at the moment. So it's something hopefully we'll get a handle on when we're --

DR. IRWIN: Right. And then if I could just go through the few of them that I have. On the door open operation --

MR. KASSIDAY: Um-hum.

DR. IRWIN: -- you described a number of complaints on Slide 10.

MR. KASSIDAY: Yeah.

DR. IRWIN: Are there common sources, for example, manufacturer, model, or does this run the gamut of --

MR. KASSIDAY: It seems to be fairly well distributed, as far as I recall. I don't have the data at hand. I mean, we could check on that.

DR. IRWIN: Great. And then on Slide 13, on the door safety interlock monitoring requirement, I'm trying to make sure I understand. Does this subsection require that both interlocks are monitoring and that only one can continue to monitor and one can fail?

MR. KASSIDAY: Both interlocks will shut off microwave power when they're both functioning properly, and both interlocks are monitored by some sort of feedback circuit --

DR. IRWIN: Okay.

MR. KASSIDAY: -- that if both of them failed, that circuit will then completely shut down the ability to turn the oven on basically, turn on the microwaves.

DR. IRWIN: So it requires both to fail before it shuts off?

MR. KASSIDAY: I think that's what it says.

DR. IRWIN: It's a little unclear.

MR. KASSIDAY: Shall cause the oven to become inoperable if the required safety interlocks fail. So it's possible that manufacturers will put that only on one, it looks like, because it's plural but parentheses. So yeah. So it could be that they have a primary and a secondary interlock and the primary may just -- may not be -- or the secondary may not be monitored but would shut down everything but lights and so forth. And then when the second one fails, everything goes out.

DR. IRWIN: Okay, thank you.

MR. KASSIDAY: Yeah.

MR. ALDRICH: Yes, Robert Aldrich.

Is there a technical reason why somebody would put an insulated wire through this? Is this something that's been documented as something that people have tried for a legitimate reason or is it just --

MR. KASSIDAY: There wouldn't be a legitimate reason that I can think of.

MR. ALDRICH: So this is just, I mean, a hypothetical concern that could be a hazard?

MR. KASSIDAY: For example, if children are operating the oven and you have a stack of pipe cleaners next to it for unknown reasons.

MR. ALDRICH: Okay, I didn't know.

MR. KASSIDAY: And I'm pretty sure that's where that came from, looking at the historical records. As I said, the original ovens, there were some on the market that had no glass or Plexiglas between you and the oven cavity, just a wire mesh.

MR. ALDRICH: Okay, thank you.

MR. KASSIDAY: Um-hum.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

I was one of those children who put things where they weren't supposed to go, just to see what would happen. And some of the earliest accounts for microwave oven safety issues were when a child would place a graphite pencil through one of the holes, and the graphite would act as an antenna pulling the microwaves out and radiating it out and heating the child. So with that in mind, realizing food burns and things like that, I see the wire insertion probably as a historical thing where there was no glass or plastic in front and you could stick something through.

MR. KASSIDAY: Um-hum.

MR. KEITH: And with arcing and sparking, I suppose that for the evaluator, it would be uncomfortable if you stuck a bare wire through and you had arcing and sparking in your presence. So maybe an insulated wire was to prevent the arcing and sparking, which may not have been related to radiation emission. But I wonder if there's any thought about whether food pathway from the inside of the microwave to the outside could also act as antenna, such that insertion of the wire may not be the only issue at hand. The wire issue may be more historical in nature, due to not having a front face over the microwave screen because the holes were small enough that the microwaves can't transmit through there, unless there's a pathway for them to transmit out. But the food pathway, dribbling down through, would that possibly provide a source, and if so, could it be assessed and introduced as part of the testing?

MR. KASSIDAY: I think there have been studies looking at how often do you need to clean the seals and so forth to assure you're not going to have a leak because of food oozing through, and I believe that it was fairly robust. And one of the requirements for the information to be provided is adequate cleaning instructions. So it's sort of on the user to avoid leaving buildup there that would interfere with the shielding.

The wire insertion these days is sometimes you can get it in through the bottom corner of an oven or in through a vent at the back or from the side into not necessarily the cooking area, but into conduits which have microwave energy in them, you know, from generating the microwave energy and so forth, which is, I think, why it got revised in '75.

And that was also why I brought in the '75 reference, because, as you say, if there's now plastic or glass between you and the oven cavity, this should be a problem that's gone away. But apparently there were issues where they thought it was worth revising the standard to make it clear. So I don't know.

DR. LOTZ: A couple of additional questions. This is Dr. Lotz.

Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

Is it correct that the FDA does test for the wire insertion? That is a current testing in the standard?

MR. KASSIDAY: Yeah.

DR. McCOLLOUGH: Could you comment on why the ability to insert the wire is not in itself considered a failure, so that you don't have to test if there's enough emission when you insert the wire? Rather, if the wire can be inserted, it's a failure of the product, period.

MR. KASSIDAY: So the issue we've run into is an issue of enforcement and proof that the oven that we found as violative is representative of, say, all other production. Maybe a couple of the model lines will fail in that way, and if the manufacturer doesn't have one, they can't go back and do the test to verify that it is or isn't violative either. It's mostly a legal issue, as I understand it. So that's why we wanted to do a series of tests to develop the data to support saying if we can get a wire in, it's always going to radiate, and it's always a problem, and you need to go fix it. But the standard itself is written in terms of power density limit.

DR. LOTZ: Dr. Lambeth.

DR. LAMBETH: Dave Lambeth.

So I'm a little confused about what you -- I mean, people always abuse products, the example with children doing these sorts of things. And I'm sure that when you stick a wire in there, depending on how you stick the wire in and the length of the wire and the gauge of the wire and everything else, you're going to get different results, and some of them probably are very bad, and some of them are probably harmless. So the real question is I don't understand what the standard would be for this abuse of a product, how you would write that, other than to say don't do it.

MR. KASSIDAY: That, I think, was the point of that part of the reg, is to avoid the ability for people to do it, as this was something that was, as Dr. Keith indicated, occurring. So as you say, maybe worrying about insertion through other means where it's less trivial, maybe we don't need to be following up on this so much. But we do occasionally find an oven where it is possible to get a wire into an area where there would be microwave, but they've been treated in the last few years as minor violations because we don't have that backup of saying yes, you definitely are violating a performance standard.

DR. LOTZ: All right, thank you. We'll have an opportunity to discuss this a little more after the next presentation. Let's move to Dr. Howard.

DR. HOWARD: My name is Lowell Howard. I'm old enough to remember having a microwave oven, one of the -- my parents had a very early one, and they had RF gasket seals. So the older microwave ovens, the one that I remember when I was a child, had an RF gasket which was soft and easy to push things into. Modern ovens adopted quarter-wave choke seals, and they have basically a flat door where it's inherently hard to stick a wire. So maybe perhaps the purpose of the reg -- and I'm just speculating here -- it's not to tell them how to achieve this. Where the goal was to have low emissions, they don't want so say, oh, you need to use a quarter-wave choke seal, because you could seal the oven by a variety of means, and one of them would allow you to just run a wire right inside there. So perhaps that was the intent of the original writers of the regulations.

I'm here to talk about wireless power transfer. I do lasers. I'm in the Magnetic

Resonance and Electronic Products Branch in OIR in CDRH, and I'm going to talk about some initial efforts, early efforts in wireless power transfer investigations. Let's see here. Okay. And I'm here to just inform the Panel of our early investigations.

Wireless power transfer, it's an old idea. It goes back to Nikola Tesla. I looked at his old patents; they're somewhat interesting. It's a very old idea that's been around, and it's coming back just in time to charge our many battery-powered portable devices, and many of these have implications and uses in healthcare environments, and we'll key on that a little bit today.

So rather than get too far and too deep into the technical weeds, I'm just going to divide chargers, and there's a very broad variety, and it's hard to put them and categorize them into bins because they cover a wide variety of frequency ranges from as low as 20 kHz on up to 5.8 GHz currently. So I'll be a little technically incorrect and just call them either the proximity type, and then for the antenna people here, these will be either induction fields or near fields, and the directed or beamed type, which use a directional antenna or some space diversity scheme to broadcast across -- in the radiating far field, to transfer energy as far as 10 m or even further.

Potential benefits: In order to understand the full risk profile, it's useful to take a few minutes and talk about some of the good things that can come out of these, primarily from eliminating connectors. Once you're eliminating connectors, it becomes much easier to hermetically seal a device. Sterilization becomes much easier, and this is going to have wide-reaching implications in healthcare. Cables are always a hazard as well as being difficult to keep clean. And a reduction in battery size can -- you can have smaller batteries, which leaves more room for electronics.

So the first type are probably the most familiar. These are basically induction fields. This is essentially a transformer where you have two coils. These have entered commerce.

You can buy them for charging your cell phone. Typically something in the neighborhood of 3 to 5 W of power is transferred. There have been a couple of competing industry consensus standards, which seems to have slowed market acceptance. But primarily the features are that these devices need to be in near physical contact, where they need to be -- basically, your cell phone is placed in contact and fairly well aligned with the transmitter coil on the pad.

And next we move to a somewhat newer technology which are called resonant proximity chargers. These use near-field RF at higher frequencies, and they use the phenomenon of electrical resonance to enhance the range of the device. And typically, these could be something as large as a pizza box, where the gaps between the transmitter and the receiving coil could be as much as 10 cm to 20 cm. It could be farther, but efficiency tends to drop off. Wireless car chargers that are on the cusp of entering commerce fall into this category of devices. These are being investigated by the Department of Energy. There are some links. And there's also a Federal Transport Administration report which is highly recommended, and you can look up that PDF in the references. But what's interesting to note from a rad health standpoint is that large amounts of power, up to 20 kW, can be transferred with these devices. It's enough to charge the battery in an electric car.

And lastly we have directed, basically free space power either by microwaves or lasers. Again, it's an idea that's been around for a while. Back in the late '60s, NASA and various government contractors that were doing aerospace started looking at the possibility at least, of beaming solar power from outer space from geosynchronous orbit onto a site on Earth, and they achieved, using a rectifying antenna, 84% conversion efficiency, and this was back 42 years ago. So the sun shines much brighter out in space, and the idea was to beam it down. These are old ideas that have been around, and they keep coming back, and people continue to look at these systems.

Here on planet Earth, however, we have a much shorter range. There are some devices that we're aware of that are getting close to entering commerce that are 2.4 GHz or 5.8 GHz, that can beam power around a room and charge batteries and cell phones and smoke detectors and things like that. So it's an interesting technology.

We also have laser-based power beaming systems, power delivery systems, laser-based power delivery systems that can power devices around the room, cell phones and again batteries and devices that would -- portable devices that would be in a hospital setting. And primarily they do these through infrared lasers.

So possible risks for the Panel and for us to be aware of: You know, generally, first is just basically classification; it's difficult to classify these things, and we have to learn a lot more before we're able to effectively classify them. Generally, the lower-power ones pose lower risk, and the higher-power ones would pose a higher risk, but we're talking about, in many cases, it's a near-field system. So you have to fully evaluate the electric and magnetic fields in the near field, and these are not simple things to specify.

Some of our questions: Potential risks would be inductive heating, what happens when metal conductors, rings, implanted medical devices, either passive or active, steel-toed safety shoes, things like that, are placed inside a proximity charger's gap where the fields are quite high. Would there be heating effects? Would there be any problems associated with that?

Moving on, wired power systems in healthcare -- before I get going into this, wired power systems, just conventional wired power in a healthcare environment has many codes, NFPAs. One of them is many standards for grounding of equipment, grounding of wiring, and control of leakage currents. And we need to make sure that wireless power, when it becomes adopted into a healthcare environment, gets the same level of attention and detail as wired power has over the years.

Electromagnetic interference with active medical devices or disruption of device communications is a concern at the FDA. Obviously, your definition of harmful interference is a little bit different if the device being harmed is a pacemaker. And these are things that are a little -- I'm not an attorney. These are things that are regulatory -- from a regulatory standpoint may be unclear.

Our engineering controls, if they are needed in the wireless power transfer systems, if they have engineering controls in the name of safety, are they sensitive enough, reliable enough, and do they act sufficiently quickly enough to prevent injury? Do current consensus industry standards adequately address electromagnetic safety of these new products? On the good side, what I've seen in the publicly available information is that people are aware, they do seem to be aware of consensus standards, and they are forming consensus standards. We haven't had a chance to evaluate them since we're at the early stages and really can't make a comment as to whether or not these are good, and we consider these to be safe standards.

So what's relevant, though, what's interesting is if you look back in the regs from 1976, they mention power transmission in the C.F.R. as an example of an electronic product, both at RF lower frequencies and microwave power beaming. As I said, the microwave technology, microwave beaming technology goes on back to the late '60s, in fact, even '50s when it was being investigated.

Laser power transfer products are covered under the current laser regs, 21 C.F.R. 1010 and 1040.10 and 1040.11, and the IEEE standard, which is about as old as I am. And there's a new standard, the SAE J2954, which is a new consensus standard for automotive chargers up to, I believe, 20 kW.

We would like to investigate -- we are investigating this using publicly available information. We'd like to investigate a little more because we have a mandate to protect the public health with EPRC. You can consider certain products like microwave ovens. There's a lot of public concerns over these, especially back in the early days. Perhaps one of the reasons they became so successful and they're regarded as such safe products is because of laws and regulations as EPRC. Microwave ovens are safe enough to -- you leave it in your kitchen and you let your kids play with them. It's one of the safer products out there. But we need to know more about new technologies, and we need to evaluate them, and we need to know if more attention is required to assure public safety.

And finally, wireless power transfer: In the Department of Transportation, there's obvious -- they're looking at putting things like electric chargers -- and they're in the early stages of this, mind you, but they're considering putting it into public infrastructure, and the public needs to be assured that it's safe. Before it goes into public infrastructure, there needs to be discussion and public comment on these issues.

So I'm very pleased to see that we have a good selection of experts on this subject here on the Panel, and so we would like to know what the opinion of the FDA's wireless power transfer safety concerns are and your recommendations moving forward.

Leaving this a little more broadly, you know, what sort of -- we are doing an initial information-gathering activity. What sort of output from the FDA is appropriate, would you consider appropriate? Would it be a reporting performance standard, which may be a little ways down the road, or a voluntary consensus standard adoption?

We also are interested in what special concerns you might have for wireless power transfer and its adoption in the clinical environment.

And finally, are there similar products or product types known to the Committee that also require attention regarding radiation safety?

So I'll return it --

DR. LOTZ: Thank you, Dr. Howard.

We have time for a few clarifying questions from the Panel, if there are such.

Dr. Stein.

DR. STEIN: Have you tested and measured around any of the in-commerce marketed devices? For example, in automobiles there are cell phone pad chargers, etc. And if so, what is the range of levels? Are we talking ELF? Are we talking RF?

DR. HOWARD: All over.

DR. STEIN: Okay.

DR. HOWARD: Yeah, the cell phone pads generally operate at low frequencies, and they're very similar to a modern -- any type of modern switching power transformer. So it would be pretty familiar technology, something on the order of 20 kHz to, say, 100 kHz. Generally, although not -- you know, this is not fixed. This is why it's hard to put things into a basket. The car chargers, I believe the SAE standard specified 85 kHz as a standard frequency, which is a little bit lower than what some of the other resonant chargers use. Some of these chargers use ISM bands at 6.78 MHz and 13 MHz for transfer. There's no reason why you couldn't use 27 MHz for the resonant technology as well. That's sort of the midrange. And then for the beamed power, obviously, because you have a directional antenna, you want to use a shorter wavelength, and those would be generally either 2.4 GHz or 5.8 GHz ISM bands. I'm on the regulatory side.

DR. STEIN: Yeah.

DR. HOWARD: I don't do measurements. We do have today a representative from OSEL. They're the laboratory side.

Have you done any?

MR. WITTERS: No, but we're aware of some of the manufacturers that are associated with the SAE standard --

DR. LOTZ: Excuse me, could you come up, step up to the microphone with Dr. Howard and --

DR. HOWARD: This is Don Witters from OSEL.

DR. LOTZ: -- just so the answer gets in.

MR. WITTERS: We're aware, in working with the SAE, the standards of the automotive industry, that they have done some measurements. And some work has been done by some of the medical device manufacturers who are extremely interested in this as well.

DR. STEIN: And just one real quick follow-up: Have you ever seen in any instance where there is any mitigation or controls built into it?

DR. HOWARD: We would very much like to get into that and see firsthand both the standard and what is currently available, what is coming into commerce, and have a chance to have a look at it.

MR. WITTERS: The SAE standard, they do have some pieces of it that are going into that direction that would create some kind of safety measure.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: This is Dr. Irwin here.

So I just wanted to ask about Slide 10. You talk about significant risks of injury, and you want to try to determine -- are there academics or others who are conducting research in this? Because we're clearly -- my son represents it -- entering a world where almost everything will eventually be wireless, and certainly we need to make sure we have academic research on biological effects.

And related to that, your second point there about performance standards versus voluntary consensus standards, is there anyone in the world that is trying to put some sort of management controls around these technologies now, recognizing that we have limited knowledge?

DR. HOWARD: I think it's important to keep in mind that these are emerging technologies, and sometimes there's a lag between regulation and the new technology development. It's a lot easier to start a company and get something onto the market, and then there's a lag time between that and when things react and follow. Luckily, your basic bioeffects standards, the IEEE standard has been around at least 50 years, and the ICNIRP guidelines represent best efforts from -- you know, on a worldwide basis and this would -- you know, it falls into there somewhere. I'd like to see more in the public domain about some of the -- particularly below 100 kHz, I'd like to see more on high H fields in that range, you know, especially particularly 85 kHz or so.

DR. LOTZ: Go ahead, Dr. Faraone.

DR. FARAONE: Antonio Faraone.

Slide 7, you indicate that more information than power density, a specific issue, may be required. Are you considering evolution of SAR antenna fields, other metrics other than --

DR. HOWARD: SAR may be appropriate. Because it's near field, generally you need to evaluate the electric field as well as the magnetic field. You need a full set of measurements and probably some computer modeling to determine SAR. I think this is a bit of -- you know, this is something that clearly needs some work.

DR. FARAONE: That is exactly what we are also considering.

DR. HOWARD: Yeah.

DR. LOTZ: Dr. Linet.

DR. LINET: Martha Linet.

In Slide 10 you talk about significant risks of injury. Could you elaborate a little bit about that, what you mean?

DR. HOWARD: Yeah. In the regulation, the regulation for electronic products early on, it says if there is significant risk to any person. And I'm not a Center attorney, so at the end of the day, regulations are words, and words are things that attorneys spend a lot of time going back and forth over at government agencies, so I'll leave that to them. But your definition of significant risk, there may be a bioeffect significant risk, and that may be what electronic product radiation is -- you know, is something that's being considered. However, if you have an implanted medical device, your definition of significant risk to electromagnetic interference may be different to you personally. And so this is something that, from a regulatory standpoint, is bound to get interesting as we progress.

DR. LINET: And a follow-up question: You mentioned or your colleague mentioned that there is some interest in doing measurements, but in fact -- and Dr. Irwin mentioned that there is a need for measurements, but what are the measurement studies? As far as I am aware, the production of these emerging devices happens a whole lot faster than studies carrying out to look at not only the actual measurements, which of course vary in time and space, but the relative importance of the measurements in regard to other devices that emit these types of fields.

So the public who contact us are quite concerned about what is the proportion of the entirety of exposure, because we're all exposed all the time. But what is the proportion of the exposure due to these specific emerging devices compared with other devices that emit these types of fields? And I wonder if FDA has done some thinking about this and some targeting of or at least recommending work on measurements actually to humans, not just to laboratory animals, just to give a sense of what are the exposures?

DR. HOWARD: Well, in terms of from an RF standpoint, you worry about the transmitter that's closest and the biggest, you know, the most powerful transmitter in the room, and the one that's closest because of $1/r^2$. Some of the midrange power transfer devices are 30 to 50 W RF transmitters at HF frequencies. The risks on that, people have been working around things like vinyl seam sealers for a very long time, and the RF effects in that range are very well known.

DR. LINET: Well, you're talking about occupational exposures, and I think I'm talking about general population exposures.

DR. HOWARD: Right. And there's also healthcare as well. Right, you're talking about something in your home on either -- you know, we don't know. I don't know. I can't comment as to what the duty cycle of that -- the duty factor would be. It's also worth commenting that in a healthcare setting, if these are in a hospital room or if you're an ICU patient, you're not going anywhere. And so this is a sort of thing when the standards have integration times per exposure, this needs to be looked at to make sure it's also suitable for healthcare environments.

DR. LOTZ: Let's go to Mr. Keith.

MR. KEITH: Sam Keith.

On your Slide 7, you're addressing possible electromagnetic risks, you're addressing metal conductors. Is there research or anecdotal evidence that EMF couples with functional or decorative items such as metal earrings, metal necklaces, metal belts, steel-toed shoes, and the like? And what drives the concern about this?

DR. HOWARD: Well, the inductive chargers, if you're looking at a 7 kW wireless charger for a car, an electric car, for instance, it would be in the vicinity of your toes and what if you -- it's not uncommon to imagine you could drop your keys and something could roll under the car and you'd be reaching in there into that gap. That would be a worst-case scenario, but these things happen.

DR. LOTZ: Mr. Aldrich.

MR. ALDRICH: Yes. I see that in grouping these together, we do speak also of directed beams, laser beams, for example. It seems to me that this subcategory would be significantly different in how it would need to be considered for any type of regulation, and I don't know that it necessarily fits. When I first heard this, I was wondering, are we talking about the possibility of regulations for the source or the receiver? You know, I know NASA is using lasers to charge batteries of craft that are on their way to Mars, for example, and that's not really a near-field application by any definition.

DR. HOWARD: Right.

MR. ALDRICH: So if we come up with something or something gets brought up, there's going to be quite the dichotomy of what design requirements may be required.

DR. HOWARD: Yeah, I could probably classify this as -- the lasers are already covered by laser regulations in electronic products. So they're in this bin because they are being used as wireless chargers, but that's already covered. And so any type of investigations or if there would be any new regulations, that would be under the RF to microwave range that's not currently regulated. But lasers are currently -- the existing regulations cover those adequately.

DR. LOTZ: One more question from Dr. McCollough, and then we will, I think, take a short break.

DR. McCOLLOUGH: Cynthia McCollough.

One of the statements on Slide 11 that FDA would like to do is inform manufacturers that they are subject to these electronic product radiation control provisions. Has there been interaction to date with manufacturers of any of these types of devices, to learn about studies they may be performing, because it sounds like there's a lot of data missing that's not known yet, and are these manufacturers aware of the potential concerns, and are they investigating?

DR. HOWARD: Well, what we're doing today is informing the Panel. We've been looking at publicly available sources of information so far. So I think it's appropriate. You know, we would like to speak to trade associations and industry groups and these manufacturers and their representatives and get that information.

DR. LOTZ: And one more from Dr. Stein.

DR. STEIN: From what you know, is the impetus for bringing this forward into commerce, do you believe, out of convenience because it's easier, simpler to recharge, or is it because it's more energy efficient? And on the energy efficiency issue, has there been any indication that it actually is more energy efficient or the reverse?

DR. HOWARD: I would say, primarily for consumer products, convenience and reliability. As an engineer, connectors have always been a key problem; it's a reliability problem, and if you can make connectors go away, your life is good. From a healthcare standpoint, enhanced ease of sterilization, having something hermetically sealed; you can get hermetically sealed connectors, but they're quite expensive. And so it just makes it easier to have a smooth surface that's easy to sterilize.

Efficiency, you're always probably going to lose a little bit as compared to wire connection. So the efficiency the Department of Energy has looked at. I believe they've published up to 94% efficiency. There's a DOE spec. ENERGY STAR, I think, requires 90% or higher, and that was important for them in their project work, their research project work that they published.

DR. STEIN: Thank you.

DR. LOTZ: Thank you, Dr. Howard.

We will have a chance to discuss this further in a little while. At this point we'd like to take our morning break. And so we're running a few minutes behind, so we'll shorten it slightly and take a 10-minute break. By my phone, that would be we would reconvene at 5 minutes after 10:00.

(Off the record at 9:54 a.m.)

(On the record at 10:05 a.m.)

DR. LOTZ: This is Dr. Lotz again, and I'd like to resume the meeting. We will now proceed with the Open Public Hearing portion of this morning's session. Public attendees are given an opportunity to address the Panel, to present data, information, or views relevant to the meeting agenda.

Commander Anderson will now read the Open Public Hearing disclosure process statement.

CDR ANDERSON: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency in the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address the issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

Thank you.

DR. LOTZ: For the record, we have a request from one speaker to speak at this first session. We ask that you speak clearly to allow the transcriptionist to provide an accurate transcription of the proceedings of the meeting. The Panel appreciates that each speaker remains cognizant of their speaking time. And our speaker this morning is Jim Shepherd, who's speaking on behalf of Sperti Sunlamps.

Mr. Shepherd.

MR. SHEPHERD: Thank you, Mr. Chair. Good morning, ladies and gentlemen of the 2016 TEPRSSC committee. Thank you for your time.

My name is Jim Shepherd. A little background, if you will. I'm the President and Owner of KBD, Incorporated. We manufacture medical devices, sunlamp devices, and have been doing it for -- I've been doing it for over 25 years. The company has been doing it for over 40. I am a U.S. representative to TC 61 Maintenance Team 16 on the IEC Commission. Also, I have contributed to WG 30 for TC 61 at IEC. I'm President of the Ultraviolet Light Research Foundation and a board member of the Indoor Tanning Association.

To the financial disclosure, a company has contributed to me getting here, but it's my company. So there you go; that's been disclosed.

The FDA has a proposed rule, and moving down the chronological review, as you can see from the slide, is a setting for possible decision errors and recommendations based on outdated support, and this all supported by existing data now. The FDA published in December of 2015 a proposed rule amending the performance standard for sunlamp products, and these were based on recommendations from the 2003 TEPRSSC meeting. FDA's most recent Advisory Committee meeting in 2010, their recommendations also came forward and, I'm sure, were considered in this proposed rule, which was offered in 2015, or 5 years later.

Since these two meetings, there have been significant changes to specific items: One is the understanding of the benefits and the risks relating to sunlamp products. This is supported by many scientific public reviews and through scientific publications and also the landscape of the indoor tanning industry.

As far as an IEC overview, obviously everyone here is aware it focuses on the creation and the maintenance of manufacturing standards for many products, and of course, that includes sunlamps. IEC standards do not always appropriately consider the U.S. regulatory landscape.

The FDA, in my opinion, should be cautious in harmonizing or adopting by reference certain IEC standards for sunlamp products and are often developed -- many of these are often developed with what I would refer to as a Eurocentric attitude focus. The U.S. regulations should not refer to items directly in the European standards because the standards are a moving target and are not subject to the rigors applied to the regulatory changes in the U.S.

Here are three examples that would be problematic if they were adopted directly from IEC standards into FDA regulations.

One is the Manufacturer's Recommended Exposure Schedule. It's based on arbitrary numbers from the IEC standard. In Europe, these numbers have proven, over the years and historically, to be a moving target as different countries view different exposure levels as safe or unsafe or recommended.

Equivalency code: The equivalency code is used basically to standardize replacement lamps for sunlamp appliances. It's right now based on an XY formula. The X part of the code is quite sufficient to satisfy all the safety needs and create minimal confusion. The Y portion of this code, there are no clear photobiological, safety, or efficacy reasons for its value.

UVC irradiance: The proposed limit is beyond the capability of existing equipment to even measure it, which encumbers enforcement obviously. It would require purchase of new equipment by countries, organizations, manufacturers. This had been previously rejected in Europe, which is another example of not automatically harmonizing with.

Here are some items from the proposal that we can certainly live with: maximum single dosage that's referred to in 1040.2 at those items; the change in the maximum timer interval, which they have computed change of the UV dose and its measuring method and the change of the current maximum timer interval.

In consultation with the FDA, I would ask that you do not support the pending changes to the performance standard.

Thank you for the opportunity and your time.

DR. LOTZ: Thank you, Mr. Shepherd.

Committee members, do you have clarifying questions for the speaker?

Mr. Murphy.

MR. MURPHY: In one of your earlier slides you showed that the standards were first developed, I forget, 2005, something like that; am I correct?

MR. SHEPHERD: The recommendations came out in '03.

MR. MURPHY: In '03, okay.

MR. SHEPHERD: Standards were submitted for publication in December of '15.

MR. MURPHY: I'm a little unclear as to are you saying that maybe some of the technology -- some of the scientific safety studies now have information that we didn't have back then? Or is it perhaps that FDA has not kept up with this, or the FDA does not have the expertise in the field? I'm just wondering what the differences are between what you're proposing and what FDA is proposing.

MR. SHEPHERD: Well, there are a couple of ways to approach that. One is that the information and data that are in existence now was not in existence then. To reply to the fact that FDA did not see, review, and take into consideration all existing data is probably not true. They probably looked at what was there to be looked at, at the time, but we're talking 13 years in the scientific field of reviewing ultraviolet products, and in particular sunlamp products, that simply couldn't be confused and used into anything moving forward, if that's what they looked at. I would have no way of knowing if any of the ensuing publications were reviewed before the 2015 publication. I would not know that.

DR. FARAONE: Good morning. Antonio Faraone.

In several places you mentioned European standards, but in reality IEC standards are international standards. They're not European based. So I mean, I guess you could clarify that IEC is a worldwide standards organization. It is frequently heavily influenced by European members, as far as I can tell from my experience, yes.

MR. SHEPHERD: Yes, sir. I'm sorry, the question, I didn't understand it, or it's just a comment.

DR. FARAONE: That was a clarification. I mean, you mentioned -- you make reference to European standards while naming IEC standards, but IEC is not a European entity. It's based in Europe, the headquarters, but it's an international, worldwide standardization organization.

MR. SHEPHERD: Correct. And in harmonization --

DR. FARAONE: But it's still a standardization organization.

MR. SHEPHERD: Sorry. Yes, sir. And with the harmonization within any industry, I think it's important to foster trade, worldwide trade. I think standardization is important to do that. My point here, if I didn't do it correctly, was to not automatically accept these decisions at an IEC standard level moving forward, to make it part of a regulation because that standard might have been developed without taking into consideration some FDA rules that exist.

Economic impact: There is never discussion of economic impact, at least in the committees that I've served on at IEC, when you're moving forward with a standard. It could be possible to have a standard that would come forward that would create an economic impact on an industry in America that wasn't used in consideration of creating the standard. That would be one example I could think of.

MR. KEITH: Sam Keith.

I too noticed the word "Eurocentric," and I guess I would assume that a lot of sunlamp products are manufactured in other countries such as China, which would not be associated with Europe. But I would assume that you kind of meant other parts of the world other than the United States. In your capacity, have you engaged with regulators in other countries or organizations in other countries to see how -- what their concerns are and what their solutions are to ensure the safety of sunlamp products? You know, not only the IEC or ISO, but different manufacturers. I assume you're associated maybe with manufacturers. But what sort of relationship do you have with the manufacturers in other countries that could help benefit U.S. safety in the sunlamp market?

MR. SHEPHERD: I personally have not. When you go back to the regulators, I have not had any contact with them as far as a regulation is concerned. My only contact would be through the standards organization and through the safety organization.

One of the things that they don't do in other countries -- and to Mr. Miller's opening slide regarding TEPRSSC. We are in that family where we fall under both of the organizations. We are a medical device, and we are a radiation-emitting device, so we answer to two masters. I think that holds pretty strong credentials when you're talking about the safety. Forget about efficacy. We don't consider that -- that was a tongue-in-cheek remark -- when we take in the safety of the individuals who are going to be using the equipment. So there are two sets of rules, not completely different, but not often parallel, that we have to own up to in the sunlamp business. But from a foreign standpoint, no, sir. From a foreign regulatory standpoint, I would be completely ignorant.

MR. KEITH: Well, not only the regulators, but also the manufacturers.

MR. SHEPHERD: I have conversation with manufacturers, and obviously, there are manufacturers that sit on a couple of the committees that I work on, so through that effort, yes, and we have discussion about that. But a regulatory body, again, the separation of the safety standards with regulations, I think, is my point that I would like to drive home on this. Just because you are creating a standard to manufacture a product by, it may not be strong enough, for the most part, in a regulatory environment in America. So that works the opposite for you if we automatically harmonize or adopt. So now we're taking a step backwards as far as safety is concerned. It could happen that way. Unlikely, possible, but could happen.

MR. KEITH: So to follow up on your harmonization, are you defining harmonization as totally accepting or just considering IEC guidance?

MR. SHEPHERD: A description of harmonization would be to accept the harmonization concept and to review before acceptance or adopting.

DR. IRWIN: This is Bill Irwin.

I'm interested in your point about being subject to both electronic product and medical device radiation. Can you estimate the fraction of sunlamps that are used for medical purposes versus the fraction that are used for tanning purposes, primarily for cosmetic purposes?

MR. SHEPHERD: As far as a percent of total market, that would be a guess for me. There are a huge amount of ultraviolet-emitting products that are used in the medical industry. What percent that is of the ultraviolet products in the market, I don't have an idea.

DR. IRWIN: Thank you.

MR. SHEPHERD: Um-hum.

DR. LAMBETH: Dave Lambeth.

So I just wanted to clarify your approach here. So with the standards that are now being recommended and considered, are you saying that in 2003, that that was a recommendation that you would not have agreed with them in 2003 and you don't agree with them in 2016, or are you saying that you would've agreed in 2003 but there has been significant changes and now you do not agree?

MR. SHEPHERD: I think that if what knowledge existed in 2003, that the knowledge was used to create the December '15 policy standard change only, then I would not agree with it because there has been too much since then.

DR. LAMBETH: So what I'm asking you is do you feel that it's different now than it was then?

MR. SHEPHERD: Yes. Yes, sir.

DR. LAMBETH: So you feel there are things now that are known that, in point of fact, you would not have advocated back in 2003, you would not have used those in 2003 to make the same arguments?

MR. SHEPHERD: That's correct.

DR. LAMBETH: Okay. So I can read your slides, but have you conveyed that to the FDA, what those things are that are known that should be considered in specifics? I know you provided a document, but I kind of got it late, and I didn't get to read the whole thing.

MR. SHEPHERD: That's fine. And a similar or like parallel document was supplied to the FDA early on their policy before their -- during the public comment period before December '15. So a document of that size, or actually larger than that, was submitted for that with a lot of these same points. It's on record.

DR. LOTZ: I think Dr. Stein had a question.

DR. STEIN: Thank you. Toni Stein.

I just was wondering, just using the example of the protective eyewear, and is that an instance where IEC is more stringent or FDA is more stringent and what your recommendation is on that issue, as an example?

MR. SHEPHERD: I think the eyewear -- one of the things where the eyewear fell into the middle was trying to create a standard for eyewear that covered more than it needed to cover, and the effort to do that was to start covering some other things that this Committee is going to talk about as far as LEDs, lasers, and that type of thing. So when it went from a simple set of eyewear to protect from ultraviolet, now it's encumbering all of that, and I think it fell into that trap. That's one of the items that probably needs to be looked at again, not only from a follow-up standpoint but from a regulatory standpoint to enforce that. The measurements are just doggone near impossible the way it's laid out now.

DR. STEIN: Thank you.

MR. SHEPHERD: Actually, they are impossible.

MR. KEITH: Sam Keith again.

In reading your letter, most of it seemed to be related to the accessibility and availability of IEC standards to the public and anybody who might want to be concerned about sunlamp radiation, but that seemed to be most of what you were concerned about. But could you tell us like, you know, two or three major things -- inform us of two or three major things that you were concerned about in the FDA's approach here?

MR. SHEPHERD: Well, back to the slide, there are three of the problems right there, and they could turn into -- be very massive problems that are in the proposed standard change that has been submitted in 2015.

MR. KEITH: And have you given FDA any guidance as to how you would approach those?

MR. SHEPHERD: I would hesitate saying guidance, but we gave them input. Yes, sir.

DR. LOTZ: Thank you, Mr. Shepherd.

Is there anyone else in the audience who wishes to address the Panel in this particular session at this time?

(No response.)

DR. LOTZ: All right, not seeing anyone, I will now pronounce this portion of the Open Public Hearing to be officially closed. We'll now proceed to the Committee Discussion related to the topics presented by FDA this morning. Please refer to the questions provided by the FDA on these topics. And I believe Dr. Howard and Mr. Kassiday are available to -- in fact, I think we'd like the two of you to come back to the table here and begin to or continue our discussion of those topics. So I'll open the floor to the Committee for additional questions of these two speakers and draw our attention specifically to the questions they presented for the Committee.

Mr. Murphy, you're up first.

MR. MURPHY: Well, one thing I've learned with my work in lasers is that everything is never as easy as it seems, so I hope I won't be too cavalier with the microwave. Your Question No. 2, what are your recommendations regarding our intended actions? And your question about the wire insertion test, it just seems logical to say, you know, you just can't insert a wire, and you guys don't have to measure it. If you insert a wire, it's a failure of the device. Is there any problem with that from an authority standpoint or any other FDA standpoint?

MR. KASSIDAY: I think the primary issue is direct proof that the standard has been violated, which is why we'd like to develop enough information to back that up.

MR. MURPHY: Is it possible simply to promulgate a standard -- since you're asking for changes, I guess, to promulgate a standard that says you can't stick a wire in because it may radiate RF? And we don't have to prove it. It's just prima facie; stick a wire in, and it's illegal.

MR. KASSIDAY: It is worth considering.

MR. MURPHY: And I'm sorry if it's too simple, but --

MR. KASSIDAY: Okay.

DR. LOTZ: Go ahead.

DR. FARAONE: Thank you. Antonio Faraone.

You mentioned that, if I understood correctly, you have not done any measurement of the potential emissions due to a wire insertion. Have you not even done any test to see whether a wire could be possibly inserted?

MR. KASSIDAY: I'm sorry. Yeah, we haven't recently -- I haven't got good records on what was done before -- done any measurements on emissions with wire insertion. We have been consistently testing to see if wire insertion is possible and have found ovens where that is possible.

DR. FARAONE: It is possible, okay.

MR. KASSIDAY: Like the most recent one, as I recall, was the bottom corner --

DR. FARAONE: Okay.

MR. KASSIDAY: -- under the door. And that may or may not be related to individual ovens that may or may not have damage in transit, which is still relevant because the oven is still not supposed to leak by the time it gets to the consumer.

DR. FARAONE: Yeah. And why didn't you do any measurements like with a field probe to see whether, with or without the wire, there would be a difference in the field outside of the enclosure?

MR. KASSIDAY: So as I said, I'm covering this for our expert on the issue. I haven't directly talked to our laboratory people, but my understanding was there is a safety concern.

DR. FARAONE: Okay.

DR. LOTZ: Mr. Savic.

MR. SAVIC: Stan Savic.

Rather than an insertion from the outside of wire into an oven, have you considered and have you done any measurements with the wires of the type that might be used as wire ties, for example, on a bread package, and if you insert bread with that type of a wire tie, with that wire tie perhaps getting caught in the door and maybe even sticking out of the door, have you done any measurements and any considerations of that type of situation?

MR. KASSIDAY: Not specifically, but I'll make a note.

DR. LOTZ: Let's go to Dr. McCollough.

DR. McCOLLOUGH: I agree with the comments about having wire insertion alone being the standard for failure, first of all, because it's not a good idea to be sticking wires in electronic devices, period, whether or not it's a microwave cavity or not. But also it seems to put the onus on the FDA to develop tests, maybe a difficult-to-measure test, from the background material that we read, and also a test that would cover all kinds of different wires in umpteen different configurations. And I think that's not a realistic burden of proof to put on the FDA. But again, rather, you can stick a wire in and it opens up the door enough to open a door lock. It should then go to the door interlock part of the standard, that it shuts the microwave off.

MR. KASSIDAY: Oh, oh. If you insert something that opens the door without triggering the interlocks, that's also covered in the standard, and that is something that we expect manufacturers to test for, and we do check.

DR. McCOLLOUGH: Yeah. So it would jump over to that situation.

MR. KASSIDAY: Right.

DR. McCOLLOUGH: But if you can insert one in and it doesn't trigger the interlock, again, I think that that is enough of a standard to hold manufacturers to, rather than having

FDA try all of these different measurements of combinations.

MR. KASSIDAY: Thank you.

MR. KEITH: Sam Keith.

I would submit to you that perhaps this wire insertion thing is a historical thing based on the time before the plastic or glass panel was placed in front, and I'll encourage you to go back historically and see, if that's the basis of the wire insertion rule, that it be totally removed, because I would also submit to you that I could place a little wire inside the microwave and close the door, and it accomplishes the same thing as you trying to insert the wire, which would be an operator type of way to defeat the method to prevent microwaves from being emitted. So if I can place a wire in there and close the door on it, I see no difference than having the door closed and trying to insert a wire in.

So I see no real benefit of having that as a rule. I think it's just placing an undue burden on a regulatory agency to try to defeat something that is easily defeatable by anybody who wishes to take a telephone-sized wire and place it in there and close the door, which is accomplishing the same thing, resulting in emission of radiation outside. And it doesn't have to be an insertion through a couple of right angles, which essentially makes it very easy to accomplish.

MR. KASSIDAY: Well, I don't necessarily disagree. The standard is written so that it is insertion from the exterior without a bunch of bends in it. But as you say, you can certainly defeat it by putting a wire in it directly and closing the door.

DR. LOTZ: Dr. Lambeth, do you have --

DR. LAMBETH: Well, I actually had a question on the other subject, but now you've stirred my thoughts on this a little bit, and my understanding was, in 2016, there were something on the order of 40 microwaves that failed, reports that they failed, without knowing really what was bad about them because you can't see them.

The wire is sort of the same way. I don't know if there were any reports on anyone ever sticking this wire and having it out, but it seems like -- I tend to agree with Sam, that it seems like the regulation that says there shall be no emissions of microwaves greater than such and such, whether it's due to a wire or due to anything, probably covers the boat, I mean covers everything. And whether you have a regulation saying inserting a wire seems, as you say, so many ways to do it, that it becomes a burden to your own agency to try to cover all of these things. It's really the manufacturer's responsibility, okay, to do his best to make something so that you won't have these accidents, but you can never thwart everybody doing bad things. You know, you can't account for all of these things. And so it just seems like it puts the burden on the FDA to chase down all of these ghosts that you never know are going to be around. It's sort of like looking for all the possible phantoms. I just don't see how you accomplish it, you know, in any reasonable resources. So your regulation that's there now seems to be sufficient. But having recommendations to manufacturers that says, you know, it actually should be built so that you can't easily do this would be fine.

DR. LOTZ: Dr. Irwin.

MR. KASSIDAY: So are you recommending that we change the reg or write a little bit more guidance to be clear about what we expect, or remove the reg, you know, that part of it?

DR. LAMBETH: Yeah. Well, my thoughts about this is that you can't write a reg, okay, that's going to cover all circumstances. And if you write one that says you cannot insert anything in any manner, okay, it becomes a burden on the manufacturer that's probably unreasonable, right, because I consider -- I agree with Sam, insertion is one thing. Another thing is you put it in there and slam the door, you've got the same problem, right? And if you're just trying to protect the 3-year-old from sticking a wire in, you know, that's a different situation than the person who's thinking about what he's going to do or who's just being curious and does it. I think it's a burden on the FDA that's probably impossible to achieve, or if it's written incorrectly, it becomes a manufacturing cost burden that we shouldn't bear.

MR. KASSIDAY: So I guess what you're really saying is that we should only pursue this aggressively when it's trivial to insert the wire.

DR. LAMBETH: Yeah.

MR. KASSIDAY: In other words, if it's obvious to a 3-year-old, they would just -- without having to struggle at all, then that's a problem. And if it's not obvious to a 3-year-old, let it go.

DR. LAMBETH: How many microwaves were sold that had -- I mean last year, and we have 40 that have sort of a phantom thing about the latches. There's this probabilistic issue that just becomes very difficult to deal with.

DR. LOTZ: Others commenting?

Dr. Irwin.

DR. IRWIN: Just a thought that it's really easy for anyone to stick a metal knife into a toaster and likely suffer significantly similar consequences, maybe worse.

But the question I had was has anyone determined that the 170-degree angle was necessary, because if you did have bends in the wire, it would not be a conductor of induced current. It's odd to me that the regulation describes this essentially straight wire at 170 degrees or more.

MR. KASSIDAY: I think that's part of the it's trivial to get a wire in there versus you had to really work at it or jam it or lock it at the door to get it through.

DR. IRWIN: Yeah, I'm thinking of lower-gauge wires that would equally be conductors of current and would easily bend to fit all of the pathways through a door seal, potentially not bypassing or causing the interlocks to fail on the door open interlocks. And I was just curious if anyone had determined that this essentially straight wire was what was necessary for the induction of current to the public outside of the oven, or if another means by -- because it sounds like everyone here is pointing out that you could lay a variety of objects that conduct current from inside out through the sealing of the door, and I'm not sure if that's the case. Does anyone on the Panel know whether number of bends in a conductor would decrease the actual value of current at the receiver?

DR. FARAONE: Antonio Faraone.

Well, it's hard to predict, but typically you would get a higher efficiency antenna if it is octagonal, like a monopole octagonal to a ground plane. So if you imagine this door with the holes before they used to have glasses, right? So this whole thing, you stick a wire in, and the wire is perpendicular to the surface to the door, which is a mesh, you would expect higher efficiency and broader bandwidth, so essentially a higher chance of producing higher level of currents.

But there can be cases where, you know, this can be actually the opposite. Maybe you have a bent wire. All of a sudden, you may have higher currents in some portions of the antenna. It depends on the length of the wire. I'm calling it the antenna. It's not really an antenna. So it's hard to predict. I really don't know why they use the 170-degree threshold, what kind of studies are there to support it.

MR. KEITH: It's my understanding from the education on this at Georgia Tech back in the 1970s that the angles really don't involve this, as long as there's the transmission path. Antennas and antenna wires can go in all sorts of directions, and the signal transmits through there. So, based on the education I had, the angles have no bearing on the transmittance. It's the quality of the conductor that leads to that, which would make me suggest that perhaps removing that requirement from the regulation might be more appropriate than having it in there to start with.

I can have a piece of aluminum foil and close the door, and it's going to transmit. You know, it just seems historically relevant but not currently relevant to the situation, as long as doors seal effectively. And as we know, doors can get warped or whatever, and you can easily take a little fluorescent light bulb in your hands, not connected to anything, and turn off the lights and run around there, and if there's any leakage, you'll see some flickers in the fluorescent light. I don't see any indication, even in the warning labels, that there's a way for the homeowner to do their own test. And, you know, I would think that removing the wire test and inserting a comment about the ability of the homeowner to do a quick and dirty assessment might be more beneficial to them.

MR. MURPHY: If I can summarize, at least for myself, some of the points, I think we're not necessarily concerned -- I'm not -- with somebody putting something in the door before it's closed and then now we have this bent wire, that the wire standard came from the early days when there was no glass, as you were saying, Dr. Keith, and that we're looking at people jabbing things through a hole. I'm not an RF guy, but maybe having that hole means there's some leakage there. And it may also be a QC thing. If the manufacturer can't make a door that -- you know, or makes a door that you can jam a wire in, then maybe there's something else going wrong with that that deserves rejection.

DR. LOTZ: Dr. Stein, I think you wanted to make a comment.

DR. STEIN: Yes. When you began, you said that the maximum performance, the MPE of 5 $mW/cm^2$ was -- your comment or in the written material was that that was where we are with regulation. And so I wanted to make the comment that in this electronic device, it began in 1998. We're now at 2016, and much has been -- much science has been revealed about exposures since then that I would suggest, too, that there be a recommendation to reevaluate that level itself. Is that still where we believe children should be exposed, or even women?

Now, over those years, we've seen an increase in health effects of breast cancer and other health-related incidences. Whether we can establish that there's a direct connection or a toxicological knowledge of that, we don't know that. But we do know that there's been an increase, and therefore we also know that there's been a lot of science since 1998 to say it's time to reevaluate that number to begin with.

And then secondly, I see this device -- you know, we're talking about inserting through the door the pipe cleaner or -- and maybe not 3-year-olds, but maybe even high schoolers who are on their adventure of understanding the world. But I would say that it's not just the microwave device that's of issue. It's now, in 2016, we have so many more devices like the microwave that emit the same type of radiation that it isn't just sticking it in there; it's a question of how do we regulate or propose to have a standard to be consistent across all products, not just the microwave, because there are many products that emit the same type of radiation?

In particular, we can think of routers or Wi-Fi routers or cell phones that have ports inside that allow the ability to have an antenna plugged in to boost it or to provide better antenna issues, usage and functionality of the antenna, and yet we have no standards on that today. And I know for a fact, in the innovation that I've seen in commerce, devices that have been used in those ports that exist in other devices -- although you're saying that the microwave doesn't have a port, it has holes that people somehow may misconstrue or mistakenly abuse and that ends up being an antenna. And I mention this because the innovations on some other products have been to try and actually minimize exposures, in fact, to redistribute the antenna that's in the devices to be less emitting.

So I just think, in general, the recommendation going forward to the Secretary should be, in all cases of all devices, that there be some type of standard and to put forth information, too, for innovation, whether or not it's possible for businesses to move forward on that or not; and if not, then to clarify with better labeling and warning, if that's the case. Right now, it's a Wild West. The warning and labeling is unclear and ambiguous, and the ports exist there. If anyone has ever taken apart many devices, they're there, and I believe that that clarification would be very helpful.

DR. McCOLLOUGH: Cynthia McCollough.

One thing that's come to mind as we're talking about this leakage is this idea of education and warning labels. People are aware that you shouldn't put metallic things in your microwave because you'd see an immediate effect, the sparking and such. They're not as likely aware that having something, whether it's a drip of food or a piece of tin foil -- well, you wouldn't put tin foil in, but they probably aren't as aware that by putting something in that door barrier, they're defeating part of the shielding and protection, and so like all the little labels that are on the door about don't do this, don't do that, I think some education towards the line of don't have things from inside the container coming outside the container worded appropriately.

But I also wanted to comment on the other question that you asked the Committee about with the door-opening standards, that I agree with the proposals that there be an indication when the microwave emission is still going and that all -- when the interlocks are triggered, that all functions shut down. So you'd asked about that as well, and I think those are wise.

DR. LOTZ: Thank you for steering us a little bit to that second question as well.

Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I'll try to answer your questions. So in terms of the first question, I think FDA should investigate it. It has to do with potential safety, so it seems to fall under the scope of the

FDA responsibilities.

Your second question is the condition regarding intended actions. I would look not only power density. Power density is a surrogate for basic restrictions, right? So for the microwave oven, it has been found that it is a good surrogate, and the limits have been established presumably in order to protect against exceeding the basic restrictions. The same thing cannot be said for the wire because it's a condition which has not been studied. So the moment you study that, and you want your study to have long-term value for the scientific community and the standards community, then why shouldn't you look at SAR and countercurrents, for example? Why SAR? Because if you have a cable -- a wire of a certain length, somebody could grab the wire, not touching the tip of the wire. If the wire is insulated and still carries current because it behaves like an antenna with SAR in the hand, for example, right, or the arm or -- so the tip of the wire, if it is not insulated especially, could produce significant countercurrents.

So I mean, those two biological and physiological significant endpoints are important, and then establishing whether there is a real danger. Like if most that can happen is a blister, I mean, it's not pleasant, but it's just a blister. If there is a serious RF burn, then it's a different story. So I mean, there is an opportunity to provide long-lasting value in terms of science on an issue that seems to be infrequent, unlikely, but possible.

Then your last question: I was actually wondering, probably, is your concern about children or even adults playing around with these devices? Because if it is children, then height might be a solution. You know, if devices are not hardened against potential improper use by children, then just placing them higher like it's frequently done today. Many kitchens could have -- if they're hardened, then they could be placed on a table, for example.

DR. HOWARD: I'd just like to comment on that last bit. We regulate manufacturers, not users. You know, it could be labeling, an informative label. But when it comes to user behavior, that really comes under a different regulatory body.

MR. MURPHY: I was at IKEA shopping yesterday, and they had a microwave that was about this high, like the face of the microwave was right where a 3- or 4-year-old might be. So they're putting them everywhere or anywhere.

On the second question that you asked about microwaves, if a microwave has failed, the oven has failed, itself, and the consumer can't tell whether radiation is being emitted, my initial thought was you could require a light or other indicator saying microwave radiation is being emitted. And then my thought beyond that was that a manufacturer would have two choices. They could do that and specifically say microwave radiation is being emitted, or under kind of the current system, if the fan is going or the light is on or there's some other indication that maybe, you know, some things that happen during microwave emission are happening, that that's the indicator. And therefore if the microwave fails in that mode, all those other things, the fan, the light, and so forth, need to go off to indicate that to the user.

MR. KASSIDAY: So yes to the sort of guidance we were talking about, but either/or. It doesn't matter whether it's an indicator or if it just makes sure it doesn't look like there's microwave coming out when there's not microwave coming out.

MR. MURPHY: Correct, because for the average non-RF person like myself, if the microwave is humming and the lights are on and I don't see any other thing, I think it's emitting microwaves. But if there's a specific light that says microwave emitting that normally I see that on and now it's not on, but the fan is going, I'm not as worried, and I don't call the CPSC.

DR. IRWIN: Yes, I appreciate the comments that people have given. I agree with you, Patrick, that engineering controls are really what you need to do. You cannot rely on administrative controls. I've seen, as someone who was in private consulting in the past, microwave ovens in all kinds of conditions after they've been purchased, and they can be quite poorly used and open themselves up to a wide variety of problems. So something that is likely to cause the interruption of the power to the fan and the light and the turntable would be useful, or it might be even more beneficial to have a light that reinforces that this is a radiation-emitting device, and if that light is on, you need to take the precautions that are described in your instruction manual that you did not read because everyone knows how to use and install a microwave oven. So I would be very reluctant to rely on administrative and more rely on engineering controls.

With regard to the first issue of the wire, I think it is more likely that the bend in the wire is useful as a quality control tool to verify you have a good seal around your door as well as preventing the normal kind of mischief that a child would have. But you cannot engineer out all of the crazy ways that a teenager might try to make that microwave oven do things that we adults would call them crazy to do.

MR. MURPHY: Patrick Murphy.

And if I could just add, and then the teenagers put it on YouTube.

(Laughter.)

DR. LOTZ: All right, I think I feel like we've got some pretty homogenous thinking here on the microwave questions. To look at that, just to summarize, my sense -- and please correct me if I misstate it -- would be, for FDA, that we do not see a need for a modified regulation dealing with the wire issue, but perhaps some additional guidance could be added in terms of recommending against it, but that there ought to be -- it would be good to investigate is this really an issue? What's really happening if a wire is inserted in terms of -- because it doesn't seem like we know the answers to those questions at this point?

On the door interlocks, I think we're of a mind that there needs to be something there added to require clear engineering controls that if something is wrong with an interlock, if there are two, either one would have to shut down the whole thing or there would be some indication, as was just described, in terms of a light that microwaves are emitting or not, or leave it, I guess, to FDA to think about how they would want to pursue that, but that something more definitive than seems to be the case at this point about interlock malfunction be required.

And with that, I'd like to turn our discussion -- barring any follow-up comments to that, I'd like to turn our discussion to the wireless power transmission question. And I see several hands going up, and I'll turn to Dr. Irwin first.

DR. IRWIN: Yes, thank you.

I feel really strongly that we need to as a community, the radiation protection, radiation safety, radiation regulatory entities in this country, put an impetus into that marketplace, if you want to call it such, to do as much as we possibly can to better understand the possibilities of human effects from these wireless power transfer technologies, and even potentially more of concern, interference with other radiofrequency radiation devices.

I am concerned, from the standpoint of the ubiquitous nature of wireless technologies, that we are starting to lose control of the complete milieu of radiofrequencies that are in our working and living environment, and that in especially a medical theater where lives are being saved, there are really aggressive actions to prevent interference, and then when very large amounts of power are especially being either radiated or transmitted by laser, that we could have severe acute injury and that we need to really investigate. Especially for electric cars, this seems to be where the greatest electric vehicles -- the greatest amount of harm is very likely.

So from the low-power arena, I'm more concerned about interference, and we need to know about that. We need academics to be funded to research this. We need manufacturers to be engaged, as they were with the wireless telephone, to fund research because, sadly, government is not going to do it. Manufacturers can assist in this. We understand that there are conflicts of interest, there are biases, but good scientists reviewing these studies can help with our understanding of it. And FDA needs to stand behind this effort to do research.

And then I think that there needs to be more from the regulatory community in this arena. We have applied administrative and engineering controls to ionizing radiation in a very comprehensive, thorough, and in some cases maybe overly aggressive manner. But we have done very little in the non-ionizing radiation arena, where we are likely to find ourselves without people who understand the science, without people who can take steps to monitor the environment for non-ionizing radiation effects and prescribe or advise on safety measures for non-ionizing radiation.

And we need to be in front of this now because it is clear that at some point in time, we're going to look around a room like this and see, wow, this place has electric outlets. I haven't seen those in decades. Or I can't believe there's all of these wires here when everybody else is using everything wirelessly. It is coming, and we need to be prepared for that. Our regulator community, our science bases for the regulator community is too weak right now to give us good foundations for protecting the public and even workers.

Thank you.

DR. LOTZ: I saw lots of other hands, so let me move around the table just to make it easy.

Sam.

MR. KEITH: Like Dr. Irwin mentioned, a lot has been done in the ionizing radiation community as far as protection efforts, perhaps more so than in the non-ionizing radiation community. And one of the important factors that the ionizing radiation community considers is ALARA, as low as reasonably achievable, so that even though there are limits for exposure, the encouragement is to reduce levels, if they can reasonably be achieved to reduce this. And I don't know whether that's adequately addressed in the non-ionizing radiation regulations and guidance, but I would encourage FDA to consider the ALARA concept in anything it does as far as assigning an exposure limit or recommending an exposure limit for non-ionizing radiation. I think that's helped the ionizing radiation community tremendously over the years, so that if you're a regulated entity, not only are you expected to live within the limits but also constantly keep looking at ways to reduce the exposure as reasonably as possible.

DR. HOWARD: I just have one quick comment on that. If it's, for example, like a near-field wireless power transfer situation, energy that's radiated is lost from the system, and it reduces the efficiency. There is built-in -- you know, built into the -- if you're looking at efficiency, you have every incentive as a manufacturer to take that philosophy to reduce the amount that's radiated because it's wasted.

MR. KEITH: Sam Keith again.

But if you look at how much you paid for your telephone bill back a couple of decades ago and how much you pay for it now -- the goal in this country is to have things at our fingertips that are easy to do right now. And so the efficiency question is, in large part, perhaps lost. And even though you can say it would be nice, it happened with flat-screen x-rays. You know, it used to be that if you did a missed exposure, you had to waste chemicals and another film, and you had to dispose of those chemicals, and there was an encouragement of the hospitals to train their technologists so that the first x-ray of the hand was what was needed. It didn't take a second or a third; you wanted to do it right.

But then when digital x-rays came on board, it's just like my dentist. When she did a bite wing, the technologist set up the unit, and all of a sudden I heard my dentist say take a deep breath and hold it. I heard a click. Keep holding it. Click. And keep holding. Click. Okay, you can breathe now. And I said what just happened? And she said, you know, I didn't like the first two, but the third one was great. I said, well, tell me what you did. She said, well, you know, it's like a point-and-shoot camera; it's just so easy. You see the first image, and then I changed this and I got the second image, and I changed this, and see how much clearer it is?

You know, in the non-ionizing arena, when things get very, very easy, people get sloppy. And it doesn't matter that my Comcast bill is close to $300. You know, I didn't have to pay very much for my telephone back years ago, and I was worried that I had to pay for actual renting the telephone. Shoot, that was nothing compared to what we pay, and we don't think about it now, for convenience. So I encourage you to not think about efficiency as the driver here, but the convenience of having things accessible to the public.

DR. McCOLLOUGH: Cynthia McCollough.

I want to comment on the specific questions that you asked. First, you asked if the FDA concerns -- what is our opinion regarding the concerns? And I think they're well founded. The document explained quite well the background, and these will become ubiquitous devices that once they're available, they're going to be rapidly adopted. And I think, as one said, FDA needs to be in front of that, or we will have a whole other marketplace develop of RF protective gear and RF protective radiator covers and such, like they did with cell phones. You can get your cell phone protective cover. Without data, without science, without ensuring a safe regulatory environment, it will be the whole cell phone thing again, but now in many different environments, car chargers, device chargers, clinical equipment.

So I think that you're right to bring this up, and I would strongly suggest it be a priority within the FDA that you get data. When we were discussing and clarifying questions, what I heard was a lack of data, lack of collaboration with the manufacturers, lack of scientific data in general. And so what is out there in the literature? What are the manufacturers doing? I think there needs to be a task group that crosses boundaries, regulatory, academic, and industry, and have information, because your next question is what do you think about regulating these, and do we need a performance standard, or can voluntary consensus standards suffice? Well, we don't know enough about the risk to be able to judge that. If it is really a trivial thing, the consensus standards might be fine, but I'm suspecting this might not be, and it will need a performance standard. So how we deal with it depends on what is learned, and that learning has to be our first priority.

You asked about special concerns in a clinical environment. There you will have to take into account almost every medical device that a patient or a family member or a caregiver could walk into the room with: pacemakers, defibrillators, cochlear implants, deep-brain stimulators. The list goes on and on. So before we know whether we have to be careful in that environment, again, we have to test with different things that might be affected by the RF. And I think that we know an awful lot about RF safety in the MR environment, and so we can learn from that and use things like SAR and our knowledge there to know where these invisible limits should be, these boundaries of where there's a field that could affect another device. So my big recommendation is that you delve right into this and get more information at an accelerated pace.

DR. LAMBETH: Dave Lambeth here again.

I concur with my colleague about learning. Knowledge always pays off in the long run. And I look at the wireless power transfer in particular and say it's coming. I don't know what format it's going to come; there are so many possible products. But somehow you need to learn enough that you can, in point of fact, say, as you do in the microwave, the emission shall not exceed this power level per power density, right, 5 $mW/cm^2$.  You have the same sort of thing over here, and of course it's dependent upon the frequency immensely, as far as various possible harm that can be done.  So it's not a simple number like that, but still something needs to be done there.  I don't know what that minimum number is, but it would be nice to have a minimum number because it would exclude probably thousands of devices from falling under regulation, and it would make everybody's job a lot easier.

We already have these things going on day in and day out, as everybody knows, but some of them have been around for a long time.  When you drive out of an exit gate of a parking lot and the arm goes up automatically, it's because you're being radiated by magnetic fields from the ground by those coils that are embedded.  Not very large, I'm sure, and probably not extremely high frequency, but nevertheless it's there, and there are lots of things out there like that.

Along with the power density part and these high-power systems for the cars that you gave an example of, which I believe are coming, there's sufficient energy there that even -- you know, does it harm us biologically?  I don't know, right, one way or the other.  You're going to find out.  But when you get to numbers like 10 kW and you get close to that with a ferromagnetic material, it yanks it out of your hand.  So there are actually other hazards involved as well with just radiation.  Excuse me, biological.  It's still a radiation form.  So I encourage you.  I don't know how you get your arms around all of the possibilities, but knowledge is where it will begin.

And once again I think, here on the clinical environment, there are so many different things out there that you could be interacting with, and we have some of that already with people walking around with these various implants and whatnot, and there are cases where they're being affected by radiation already. So yes, study it. But my feeling is don't try to regulate devices like saying it's a microwave. Okay, maybe the general word is to say it's a power transfer device is wrong because there's radiation like this. It's really not a power transfer device, but they're just out there in the sensor world or communication world, okay, if you want to call that power transfer, but you might misname it if you're not careful in that regard.

DR. LINET: Yes, there is a huge body of literature on various frequencies of non-ionizing radiation that you should be aware of. The International Agency for Research on Cancer reviewed comprehensively the animal literature and the human literature on extremely low-frequency radiation around 2001-2002. There haven't been a huge number of human studies since then, but there had been, by the time that literature was reviewed, a substantial body of experimental data and very large animal studies carried out by the National Institute of Environmental Sciences. So I refer you to all the volumes of the International Agency for Research on Cancer, which is an arm of the World Health Organization, are located online, and you can download those volumes, very important.

In 2011 a committee was assembled to review the human and animal literature and mechanistic literature on radiofrequency radiation, and they put forth a volume. I believe it was published in 2013. That takes us up to most of the human literature on radiofrequency, so I would refer you to that. So there is a body of literature that is out there.

And I think it's important to recognize that the extremely low frequency was -- scientific work was initiated in part because of the need internationally for greater amounts of electricity, and people got concerned about the increasing placement of high-power lines and electrical power plants and so on and so forth and thought there must be -- we need to study this. And so it was studied comprehensively by multiple countries doing multiple studies, and meta-analyses were done of the data for extremely low frequency. Two large meta-analyses were done, and the agency reviewed the entirety of the literature and the outcomes -- this is with regard to cancer -- and concluded that the only outcome that was consistently linked with extremely low frequency was childhood leukemia.

And so the National Cancer Institute and many other countries in the world had been monitoring childhood leukemia incidence rates to see if, with the increase in extremely low frequency, one would expect that the rates would increase, and internationally there are a small number of countries where that's been the case. But it internationally is not the case. We recently reviewed and published on this in 2015.

And in terms of radiofrequency, there's a lot of concern, of course, about cell phones, and I think it's important to recognize that unlike the situation with ionizing radiation where concern grew early after the development of the x-ray machine and continued to increase after the atomic bombs were dropped in Hiroshima, I mean, those were decades ago. So we have had decades to study ionizing radiation. The use of cell phones in this country began in the early 1980s. And so in looking at late effects, you know, we should be seeing something now. But the growth in use of cell phones really didn't occur -- there was hardly any use as late as the early '90s, and by 2014 or so there are 7 billion cell phones estimated throughout the world.

And a number of health organizations are monitoring the main cancers of concern with regard to cell phones, head and neck cancers, and the consensus is that there has not been an increase in the incidence of the head and neck cancers that were of concern, but the monitoring continues to this day.

The National Institute of Environmental Health Sciences has also done a very large animal study which was -- there was some news about it, but it has not reached the peer-reviewed literature. This was a study conducted underground in Chicago using very specially constructed cages that were developed in Europe, but the National Institutes of

Standards and Technology oversaw the development of these because, of course, when you're trying to expose animals, because radiofrequency exposures are everywhere, one has to be very concerned about what the exposures are, and this has been the situation with the animal studies. Those are expected to be reported in 2017.

Studies of cell phones have continued to this day in large cohort studies in our own institute, which is going to be launching another large cohort study seriously considering adding questions about cell phone use among other things that we are studying. Nordic countries are already carrying out very large studies on this.

You know, late effects take a long time to occur, and the studies, the best of studies take a long time to do. A short epidemiologic study is 5 to 8 years, a medium length one is 8 to 15 years, and a lengthy study would be a lifetime study, as was the case with the atomic bomb survivors. So I think that it's really important to recognize that there's not a dearth of literature out there.

And in addition to the International Agency for Research on Cancer, there are other bodies that are constantly reviewing the literature that comes out. One is an organization, a European organization called SEEN-HERE (ph.). I can't remember what the acronym stands for, but I can send the information, and again, you can download that. The report is on the internet.

And I think one of the biggest problems is education. And so one of the things that I was going to say was a label on microwave ovens, "Emits Radiofrequency Radiation," might be very useful. A lot of people do not realize that, you know, these devices do emit radiation. And the other lack of understanding is that if you just get a short distance away, your exposure levels are very low. I don't know. You know, that's a behavioral thing; that's not a manufacturer's thing. But I think that's people's understanding of these devices and the fact that they don't understand what emits radiation and what doesn't emit radiation, etc.

Now, getting to this wireless power transfer, the problem with studying these devices and that we encountered in our own work in studying cell phones is we did a wonderful, fabulous study of cell phones, and when we were just finished with it, the analog cell phones that we had studied were no longer being used and digital cell phone technology was in place. So it was a terrific historical study of very little import.

I think another thing that people don't recognize is that, for example, the cell phones, the exposures as bay stations have increased all over the world, the power goes down, down, down, the energy emitted goes down, down, down. And so, you know, again it's lack of education. Now, we ourselves produce fact sheets, and you have wonderful websites. We cite your websites, you cite our fact sheets. So there's information out there, but somehow I think it's not getting to the public.

The problem with these emerging devices is you can study acute effects probably in 2 or 3 years, but in studying late effects, you know, by the time we get going with organizing and developing protocols, really high-quality protocols for the best studies, life has moved on, you know, years are passing, and the technology will change.

So from our perspective, there are two important things that really need to be undertaken, and I mentioned one earlier, exposure assessment. We don't really have ongoing good studies of exposure to really understand, well, what are the exposures and what is the relative contribution of exposures of some of these wireless devices compared to cell phones? And there are some studies that are ongoing, and I have to say that most of them are being undertaken not in the United States.

But I recall a number of years ago when the FDA was very concerned about an animal study with cell phone use and lymphoma, you came and visited our institute, you locked us in a room, and you said we're not leaving here until you people add a cell phone component to a study of lymphoma that you're about to undertake.

So I think that federal agencies do have the opportunity to influence other agencies which might collect the data if you just say, you know, loudly enough and to the right people, we need more exposure information because we really don't know what the exposures are.  And particularly with the analogy with ionizing radiation, the concerns really should be children and adolescents.  I mean from analogy.  Now, we don't know for sure that adults are not important.  We probably all are important.  But the studies that really need to be taken into account are what are children's exposures to these devices?  So I think there are things that can be used.

Now, the other thing I always try to remind people is benefit-risk.  Everybody comes to us, risk, risk, risk, and I say gee, you know, our world has been transformed by the use of these devices.  I mean, imagine a world before the days of cell phones.  Hard to imagine, isn't it?  And should we throw out all of our cell phones because of our concerns about the radiofrequency exposure?  I think we have to -- you know, there's a balancing thing that goes on here.  So I think that part of it is to understand what are some of these devices?  In hospital settings, what is the benefit of some of these devices?  You know, it's the same story.  CT scans, all the things we're going to talk about later today and tomorrow, there are benefits to these things, and we need to weigh the benefits and the risks.

And obviously, it would be nice to reduce exposures before we even know what the exposures might cause acutely or chronically.  But I think that it's unrealistic to think that as these devices are being developed, that in a flash we can know what the late effects are.  It's not how things work with chronic diseases.  There's a latency period; it takes time to study these things.

And so I think the exposure assessment part is really critical, and I think I would like to see more emphasis from FDA encouraging other agencies to actually carry out some of these exposure assessments. And there are exposure assessments internationally going on. I just reviewed a paper over the weekend, a very important paper. I said fast track. But you know, journal publication is slow and so on and so forth. So we need to get the information out there, and we need to improve our communications about these things.

I'm done.

(Laughter.)

DR. LOTZ: Thank you, Martha.

I think we're continuing down the row there. Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I'm going to go through your questions, and I'm going to add some comments. So to get in the wireless power transfer safety concerns, obviously, those levels of power, the question about safety is important. So it's justifiable.

There was a question by Dr. Irwin about the industry proactiveness addressing these issues. It is there; I can assure you of that. And not only as a company, we are doing due diligence, looking at what is power transfer, a subset of wireless power transfer devices and systems, to make sure that we have -- to make sure about the safety and also to develop compliance assessment methodologies, typically together with the FCC, for example, to assess the compliance of those products relative to the exposure standards, exposure limits.

At the standardization level, there are at least two efforts I'm aware of, both within the IEC and the IEEE. One is about extending the frequency range of the current standard for portable devices down to 4 MHz, to at least include the 6.78 MHz frequency, which is commonly used for portable devices or chargers. And there is a new working group within IEC Technical Committee 106. It's called Working Group 9, which is specifically engaged in developing assessment methodologies for wireless power transfer. And essentially, the industry has learned from the experience with cell phones, where cell phones became very widespread before there was any standard for compliance testing. The first standard was issued in 2003, so much later compared to the introduction of the product. So the industry is very -- is proactive and is, I think, well engaged with the regulators in different regions of the world to make sure that there is a solid science-based standards framework to support the safety and compliance of these products. So the FDA effort is fully justifiable.

And you have correctly broken down the types of wireless chargers, the fact that resonant chargers are much more efficient than traditional inductive chargers, and they can provide very high efficiencies. In fact, they are very attractive for different classes of products, including portable devices. And then the far-field beamforming type of wireless chargers, which pose their own classes of challenges due to, for example, the current exposure limits imposed by the FCC. So clearly there is a need for investigations in those areas.

In terms of whether a performance standard or a voluntary consensus standard is preferable, well again, there will be standards that will be developed at the international level, and clearly, for the sake of harmonization, it would be desirable that science-based standards are adopted uniformly. So it would be -- you know, my advice would be for FDA to consider adopting those standards once they become available for the domain of which FDA is responsible, because there's another domain where FCC is responsible.

In terms of clinical environments, there is a question about potential concerns in clinical environments, that interference could be one concern, interference of medical devices. Why? Because low-frequency chargers, typically low frequencies may defeat shielding mechanisms, at least some of those. So they could penetrate shielding enclosures in some cases, while on the other hand, very high frequency like millimeter waves, millimeter-wave beamforming chargers, they could readily go through small apertures in enclosures that have not been hardened with the expectation of having to deal with these small wavelengths. So I mean, going forward, it's still in the future, but that could be one challenge in the clinical environments, even though I suspect that the moment you have to meet human exposure limits, the power density levels will be so low that the potential impact on interference on devices will be unlikely. It just remains to be seen.

The last question, whether there are similar products: Intuitively, the moment you talk about beamforming, I think about 5G. But 5G being a communication protocol and technology, they typically operate at the lowest power that allows them to provide the quality of service required, for two reasons at least. One is battery life of devices. The other one is that these communication systems are interference limited. So each device interferes with each other device because they share the spectrum typically. So essentially, the ALARA approach that Mr. Keith mentioned before is really employed in all communication systems where you really want to emit as little amount of power as possible to achieve the goal of providing good quality of service in terms of communications.

Now, you also mentioned ALARA as a potential framework to apply to non-ionizing radiation. I would disagree with that for the reason that non-ionizing radiation does not produce cumulative effects like does ionizing radiation. So the weight of evidence presented by the large amount of knowledge in this area, which is quantified in thousands and thousands of articles in peer-reviewed journals, from in vitro to in vivo to human studies, shows that the effects are temporary, only during exposure. There is no cumulative effect. And essentially from this point of view, the current limits, which are already well below the established thresholds for health effects, are already, if you wish, ALARA. But there is no need to go in the same direction as ionizing radiation for the fundamental differences between the two forms of energy -- well, the same form of energy but different frequency range. In terms of potential health effects, one is cumulative, the ionizing radiation; the other is not.

DR. LOTZ:  Thank you.

And moving on, Mr. Savic.

(Off microphone comment.)

DR. LOTZ:  We've had people waiting, I think, on this topic, so let's move along.

MR. SAVIC:  Stan Savic.

Most of the subjects were covered already, but I would just like to know, have you contacted people that are involved with RF radiation, like FCC and OSHA, that have established limits and so on, and what use of their experience can you make?

And just a last comment on what Dr. Faraone mentioned a little while ago:  I would wonder whether Dr. Linet would agree that there is no cumulative effects of, for example, extreme low-frequency fields and so on.  I think some of the studies that link leukemia and so on might have the effects of the time exposure to those low fields that they take into account also.

MR. KASSIDAY:  So to clarify a little bit, we are in contact with FCC and discussing the wireless powers as a whole, and we intend to coordinate with them in whatever direction we end up going in.

The other thing I think I really need to clarify is that we're not talking about new bioeffects here.  We just need to do the assessment on the exposures that are coming out of these for the known bioeffects, to make sure that they're in compliance with the accepted safety limits that are already out there, where there are limits out there, and look at whether there needs to be limits in the areas where those currently don't cover.  So generally we're talking about heating and neurostimulation and induced currents, nothing more.  And thank you so far for the many good comments.

DR. LOTZ:  Mr. Murphy, do you want to chime in on this one at all?

(Off microphone response.)

DR. LOTZ: Okay, I think Dr. Stein is probably waiting.

DR. STEIN: Yeah, thank you.

So I just want to go back to the warning labels and labeling issue with respect to, as we had up -- I assume we're moving to the wireless transfer now. I mean, if you think about it, how would you ever label the area? Would you cordon it off? Would you make it a building only where this would take place? Would it be permitted just anywhere and everywhere, in every school and every classroom and every nursery school and every childcare center? I'm trying to understand the exposures that we're bound to see because we currently -- you know, we're hearing on one side of the equation that only ionizing radiation has any effect on humans and that these power densities are so low that there would be no issue on humans biologically, and I personally have read many reports from the EMF portal, from -- that is sponsored by Utrecht University, put up, as well as many other sites.

For example, the EMFscientist.org, 238 doctors and scientists across the international community have not felt that way at all. They have been very concerned about the exposures on all adults, children, and see it as an issue. Especially for those that are extremely sensitive, they're finding that they don't have a place to be in society, that they don't know where they can walk because their disabilities of their faculties can't be in these conditions. So I really think that we need to think carefully about the labeling and providing best practices to make this feasible for both the vulnerable as well as the hardy and strong.

You know, our current standards, as Dr. Linet had brought up, don't address children, and you're saying that -- you know, you're questioning they don't address children? No, they were not designed -- they're for one degree temperature, not to address

-- right now, the autism rate in the United States is at 18%. And again, I can't say that this is the cause, but do you know the cause? No, we don't. So I think we need to be careful about everything that we do because our children do matter, and these biological effects beyond the one degree temperature thermal effects are beyond the scope of our knowledge at this point.

So we need to be very, very careful and label things and provide best practices for ALARA and provide the ability for innovation in our marketplace to go beyond what's being sold today.

I mean, the nice thing about microwave ovens is it's so easy to shield, compared to the low-frequency fields that we can do literally almost nothing about. And to have that ability, to have the ability to shield is super great, and we should try and be encouraging, in the U.S. alone, the innovative technological minds. And our universities have capability to go way beyond where we are today, if we allow them to. But I find that there's this fear of the risk to talk about it. I mean, like you said, the light on the microwave oven doesn't even tell you that there's radiation coming out of it. I think we need to label, warn, and allow people to apply best practices, like distance is your friend. People need to know these things.

DR. LOTZ: Thank you.

Round two, follow-up comments?

DR. IRWIN: Just real quick. I appreciate Dr. Linet's reminder of the great research that has been done on biological effect and reinforce her point that the research that I think is necessary is an exposure assessment of these new technologies to understand just how they relate. And I think it's a good starting place already, that we do have specific absorption rate values that can be a fundamental basis for determining whether or not the new applications are reasonably safe until we find otherwise.

And so I would recommend, as kind of a roundup of this session on the wireless power transfer, that those are the areas to look at, the interference with lower power equipment, especially with medical devices, and the higher power and whether there are acute effects likely to occur with the specific exposures that are there.

But lastly, to also point out one of the things that I think is lacking in this country is that FDA does a great job of identifying that items are produced effectively and that they can be used upon immediate possession safely. Unfortunately, as someone who goes to a lot of really beautiful gas stations and some really crummy gas stations that I would never want to go near again, humans are likely to let things deteriorate, things fall apart on their own, and there needs to be more, after FDA approves of these devices being employed by others -- perhaps the rest of the regulating community -- to ensure that after years of use these things remain safe. And our nation doesn't do that adequately, and the reason we don't do that adequately is that unlike ionizing radiation where there are continuing standards for use after the product is put into the marketplace, we don't have those for non-ionizing radiation, and I think that the nation needs to build in not only regulations that do this, but also that provide funds for states and other entities to go out and perform these kinds of exposure assessments after products are in the marketplace to ensure continued safety of these products once they have been put in the hands of people.

Thank you.

DR. LOTZ: I'm going to usurp the microphone here to add a comment of my own, as opposed to just managing the discussion, and that is to put in a plug. And this is not to disagree with Dr. Linet at all about the general population and others who have expressed that, but to put in a comment about the occupational arena because particularly, say, with things like car chargers and stuff, we're likely to see occupational groups that are dealing as much with these high-power transfer devices, or maybe more so, as opposed to an occasional use on a regular basis.

I've actually been a part of some recent effort to look at, not with respect to this particular technology but with respect to RF technology in general, the issue of electromagnetic interference with medical devices in workers going back to work with -- and this is an increasing number. I made a presentation to the American College of Occupational Medicine recently that was -- it turned out the room was standing room only because of corporate physicians who are dealing with the issue of electromagnetic interference with implanted personal medical devices, and I think this is a technology that will also play into that picture very much so. So just a bit of a plug from my own personal perspective on the occupational needs to be addressed in that overall picture.

Mr. Keith, you were going to add something?

MR. KEITH: Sam Keith.

Dr. Linet had addressed the leukemia studies. Back when they first came out, the researcher had related leukemia, childhood leukemia, as to what they call wire code. He didn't take any measurements but looked at the size of the telephone poles, the number of wires, and assigned that and found a direct relationship, a statistically significant relationship between wire code and childhood leukemia induction. And several years later, researchers went in there and actually took measurements and found that there was no relationship between wire code and actual exposures.

So the supposition at the time was that it was not clear whether EMF caused childhood leukemias, but perhaps it was the close density to -- close proximity to high-density traffic areas where there's a lot of diesel exhaust fumes and perhaps exposure to that was causing the childhood leukemias.

So actual measurements of things are very, very important. Don't underestimate the importance of that, that you may mix suppositions and hypotheses that may or may not be true without knowing what the exposures actually are.

And Dr. Faraone mentioned that, as far as non-ionizing radiation, there are no cumulative effects. Well, I would ask us to go back into the early years of ionizing radiation where it was first realized that ionizing radiation could cause cataracts, but there was a threshold, and if it wasn't exceeded, then that would be fine. And then as years went on, we found out there was actually more of a cumulative effect, that if you're exposed to a little bit now, a little bit later, and a little bit later over the years, you could develop cataracts directly associated with the cumulative exposure, although the hourly and monthly and yearly limits were not even close to being met. So from the ionizing radiation point of view to the non-ionizing point of view, keep open in your mind that there could be the potential for cumulative effects of non-ionizing radiation that we want to be sensitive to and not unnecessarily avoid considering it as we go down the road.

As far as relationships with other organizations, I've heard FCC mentioned. I have a good colleague from EPA who now works for FCC and was doing dynamite work in earlier years, and I'm not sure it's been continued. But the idea of having mobile platforms that you drive through areas and map the RF field in a community, I think, is very appealing to me because I know, from the radiation arena, I can take an instrument out there and I can take measurements here, and I can take another instrument and take measurements there and say, wow, there's a 25% increase in that area. Well, it may have been just because of the calibration of this instrument versus that instrument.

But if you take an instrument that's calibrated and go through the whole area, you can map it out without the concern about the error associated with the calibration. I mean, there may be an overall bias to the whole area that you're measuring, but if you use one instrument and do a whole area in a short period of time, you can get a very good overview of what the radiation is, whether it's in a room near a microwave, whether it's in a developmental area from a manufacturer, but taking measurements with considering FCC as colleagues and the Department of Energy as colleagues, because DOE is very interested in transmission of energy, too, and perhaps they've done work there that we may not be aware of.  Reach out to them.

And perhaps neurostimulation and heating are the major contributors to the potential health effects, but also I'll encourage all of us to keep in mind that there are other health effects.  The most highly studied population as far as health effects and ionizing radiation are the Hiroshima and Nagasaki survivors, and we knew that -- you know, other than the acute effects of being vaporized on the site or having ionizing radiation damage, you know, that we have discovered, as the science progressed, as epidemiology progressed, that there were also cardiovascular effects.

Back in the '90s they were thinking about doing away with the study because all we were doing was tweaking the cancer risk factors, and then of non-statistical significance but bumping up closer was some cardiovascular.  That's not an effect.  Well, maybe it is.  And then over time it's been teased out that the cardiovascular effects actually are a significant long-term health effect associated with even acute exposure.  I have a colleague, just retired, who went through radiation therapy, and it's the circulatory system that's being affected now more so than anything else.

So let's be aware that there could be also other health effects of the neurostimulation and heating that could be at play here and in the future, especially as more and more people use more and more devices and get more and more exposure.

DR. LOTZ:  Dr. Stein.

DR. STEIN:  On the special concerns, one thing that hasn't been brought up is that these are high-power devices, and it should be definitely included, the on/off, because of power quality issues of turning on very high power and turning it off and getting power surges in your line voltage that can affect -- you know, it wouldn't be direct EMI, but it would affect the 60 Hz power lines, and that should be definitely included in the studies as well as, I heard before, the continued reporting or continued safety after market, how does it do? And I think that trying to request and recommend that there be reporting, that there be follow-on reports required by the manufacturers would be really good, as well on the FCC comment that came. The FCC has an open docket right now, today, 03137, on the RF standard itself. And is that adequate? And I think there's over 500 comments from the public, from industry, from a mixture of public members, and that should be -- I mean, I didn't even read about it in any of the materials for today, and definitely cooperation and collaboration with FCC on those comments should be included in this. That was my addition.

DR. LOTZ: Thank you, everyone.

Let me see if I can kind of sum up where we are with this topic. With respect to the FDA's questions, obviously, the Panel shares some of your safety concerns and the need for attention to this emerging technology in the wireless power transfer technologies.

And it's been expressed over many times that exposure assessment and better information about what these technologies produce at the various frequencies is needed, a better collection of that information and new studies to define it, even as the challenges of a rapidly changing technology exists in that.

Interagency collaboration has been a topic to be encouraged. The aspect of regulation is one, I think, the Panel is less decided on, based more on what you find in those studies of what the technologies currently produce in that respect.

A definite concern for the clinical environment and both from electromagnetic interference but also other types of issues, even as, I think, in your presentations you explained some of the potential benefits of using wireless power transfer in that arena.

And then there has been comments to relate to other equipment.

And the one other thing I was thinking about to summarize was that even though both frequency -- both transmission types are used, that you clearly can differentiate the laser from the RF arena in these types of technologies, which was also a topic you mentioned, but also reinforced by Mr. Aldrich and others, I think.

So with that, I think we're about ready to finish our discussion of this topic.

Dr. Ochs, have we addressed FDA's concerns?

DR. OCHS: Yes, thank you.

DR. LOTZ: Thank you. We are ready to break for lunch, then, at this time. And I will remind Panel members that we're not to discuss the meeting topic during lunch with ourselves or any member of the audience. We will reconvene in this room at 1:00 p.m. I ask all Panel members to please be back at that time, and I've been advised that we should take any personal belongings with us during the lunch hour. The room will be secured by FDA staff during the lunch break, and we will not be allowed back in the room until we reconvene. So we will reconvene the Panel meeting at 1:00 p.m.

Thank you.

(Whereupon, at 12:02 p.m., a lunch recess was taken.)

A F T E R N O O N   S E S S I O N

(1:04 p.m.)

DR. LOTZ: May I have your attention, please. We'd like to reconvene the TEPRSSC Panel meeting, and I think it's our FDA colleagues that are giving us the most challenge on that.

So our afternoon session is on laser products:

- Update to Amendments to the Laser Rule
- LiDAR
- Remotely Controlled Mobile Systems
- Laser Pointers
- Lamps for General Illumination and IPs
- Infrared Applications

So we will continue with presentations by the Food and Drug Administration. Captain Hewett, Dr. Howard, and Dr. Calhoun will present this afternoon. Their presentations will be followed by a Committee Discussion.

And just as a reminder, although this is open to public observers, public attendees may not participate except at the specific request of the Panel Chair.

Captain Hewett.

CAPT HEWETT: All right, thank you. Well, good afternoon, TEPRSSC Panel and public audience. My name is Dan Hewett, as stated. I'm in the Magnetic Resonance and Electronic Products Branch, just like my colleagues before me. So I won't go on to the organizational details, but my presentation is on the update to the amendments to the laser rule.

So our history thus far is our current laser performance standard was last updated in 1985, and I'm going to refer to that as the laser rule throughout this presentation. So the laser rule is based on an outdated understanding of photobiological science and no longer reflects the current state of a technologically evolving industry. So in 2013, FDA proposed amending the regulations applicable to laser products -- those are found in 21 C.F.R. Subchapter J -- in order to update its standard.

So through this action, FDA intended to better harmonize its standard applicable to the laser industry with the current International Electrotechnical Commission Standard 60825-1, which is a standard for the safety of laser products. The proposed amendments were posted in the *Federal Register* on June 24, 2013, and we received about 40 comments on this proposed rule.

So when that was presented to the public in the *Federal* Register, a few things happened afterwards. We received notice that several IEC standards were being amended and have since been amended. Those include the 60601-2-22 medical electrical equipment standard, the IEC 60825-1 safety of laser products standard, and the IEC 62471-5 photobiological safety of lamps and lamp systems standard and specifically Part 5.

So the other thing that happened was ICNIRP, which is the International Commission on Non-Ionizing Radiation Protection, revised its "Guidelines on Limits of Exposure to Incoherent Visible and Infrared Radiation." And the American National Standards Institute, also known as ANSI, made changes to its safe use of lasers, maximum permissible exposure levels. So almost practically out of the starting block, our standard would need some revisions based on these updated standards that came shortly afterwards.

So we have been in the process of drafting a re-proposed amendment. Numerous changes have been included, and the bulk of these changes you're going to find in the briefing materials. And I'm not going to go bit by bit through those. I'm just going to be summarizing those basic amendments in this proposal. I mean in this presentation rather. But I want to say that the ones in bold type will be discussed further in my follow-up presentation on laser LiDAR, remotely controlled mobile laser products, and laser pointers.

So let's go through these fairly quickly. We have some proposals that add or define certain IEC classes that we're going to adopt in this new standard, and those are 1C, 1M, and 2M. I know everyone here on the Panel is not necessarily a laser person, so some of these classes may be a bit unfamiliar to you. So in my next presentation I'm going to go over some of those classes and what they actually mean.

But we also add finished laser product, which is a definition we had not previously had; installed laser product; laser illuminator, because that's definitely an emerging new product line; laser-illuminator image projector, that's basically something new; laser or light distance and ranging; laser pointer, which previously had not been included as a definition; laser rangefinder or speed detector or speedometer, however you want to say it, has been included.

We're defining what is a non-laser product at this point, because we have felt the need to look closely at how products are designed as laser products and how they're designed as non-laser products, and we want to make that clear to the industry.

Remotely controlled mobile laser products are also something that seems to be an emerging issue. You can imagine a drone flying along with a laser, infrared laser emitter, perhaps for a surveillance purpose. Electric toys have been defined and added. They were added previously in the proposed rule, but our proposed rule continues to redefine electric toys. And certain 1M, 2M, 3B, and 4 class limits have been applied to specific-purpose laser products. And I'll go into some more detail in my next presentation on some of those specific-purpose laser products.

We define maximum permissible exposures as the U.S.-based ANSI MPEs. We adopt portions of the IEC medical equipment and laser safety standards. Am I loud enough for everybody? Okay. Portions of the IEC lamp standard have been adopted as well. We reference ICNIRP radiation limits, which as I mentioned had been updated and revised, as well as those ANSI maximum permissible exposure levels.

We think we've improved the children's toy laser product definition as a result of a comment we received during the comment period, and we add removable laser systems as a definition. And actually, we improve it rather than add it. We refined the laser product definition, and we modified a surveying, leveling, or alignment definition, which has been in place for a long time, since 1985 and before, of course.

We retain collateral radiation definition and x-ray radiation limit because those differ slightly from IEC's standard, or rather their definition, so we prefer to keep our own definitions for those two standards. We retain a demonstration laser product definition, our laser radiation definition, our useful life testing requirement, and our requirement for failsafe or redundant interlocks. And we retain our emission indicator function prior -- we retain a requirement in our emission indicator function prior to the emission.

Okay. And the limits: We've looked at laser pointers, and we think that it would be wise to exclude certain wavelengths to decrease the public health risk from flash blinding. We also exclude certain non-applicable IEC definitions, which I haven't fleshed out exactly what those are in the briefing materials, but I can assure you, they would not be applicable under our performance standard. We exclude an IEC subclause covering products designed to function as conventional lamps.

We adopt all the IEC accessible emission limits and the IEC medical equipment standard clauses. And we require an additional warning label for 1M and 2M products. And does anybody not know what 1M and 2M is on the Panel? Okay.

We reject IEC's allowance for no remote interlock connector for handheld battery powered Class 3B laser systems. And we clarify and add "incorporation" in context with the laser product definition. And we clarify and add children's toy laser product as a failure due to disassembly or breakage. We clarify and add laser-illuminated projectors, or LIPs, as demonstration laser products. And we include qualifying and test conditions, and risk group limits.

We also require specific controls for remotely controlled mobile laser products, and we remove non-adoption of IEC's single fault conditions. And we also remove FDA and adopt IEC's security master key control requirement, the Class 3B or 4 beam stop requirement, the alternate labeling scheme, and the user information requirement.

Previously, those requirements that I just listed we found unacceptable in the IEC standard when we first proposed the rule in 2013, but since that time they have been revised, and we find them acceptable, so we're including them in the re-proposed amendments.

Okay. Well, I know that was a lot, and I had to zip through it because it would've taken all afternoon if we had gone through each one in detail. But do you have any questions or comments on the proposed amendments?

DR. LOTZ: Any clarifying questions from the Committee at this time?

DR. LAMBETH: Maybe you could speak just a little bit more about the pointers.

CAPT HEWETT: Okay.

DR. LAMBETH: I didn't quite understand when I read it, what you were trying to accomplish by that definition.

CAPT HEWETT: Well, the best thing about that is that's my next presentation.

(Laughter.)

CAPT HEWETT: So you're going to get a real earful about that in a second.

MR. MURPHY: Patrick Murphy.

A slide or two back, you had remove non-adoption of single fault conditions. I'm not sure what that means. There are too many negatives or something in there.

CAPT HEWETT: Yeah, it's a little strange, the wording. So an IEC standard basically said the manufacturers have to consider every single fault condition when evaluating their laser product. In the U.S.A., the CDRH disagreed with that for several years. But in the interest of being consistent and having manufacturers create consistently manufactured products that were all on the same level playing field for the international and U.S. market, we are adopting the IEC single fault condition.

MR. ALDRICH: Robert Aldrich.

I have, I would say, a litany of specific questions having to do with all the stuff that's covered here, but I understand that you will have follow-up information about pointers with one of the topics and other things as well.

CAPT HEWETT: Yeah.

MR. ALDRICH: Would you prefer questions to come when you're finished with all the presentations or as -- because I think some of these will overlap.

CAPT HEWETT: Yeah, let's wait; it will probably overlap a bit.

MR. ALDRICH: Okay, that's fine. I'll have questions later.

CAPT HEWETT: Plus, I have all the briefing materials right over here, so I don't want to have to dash back and forth. I just want to say, though, that we're going to have -- you know, of course, like any rule, we're going to have a comment period again. So you don't have to get everything out right here.

But sir?

DR. FARAONE: Antonio Faraone.

In the first slide, you mention outdated understanding of photobiological science. Do you have any specifics? Were these outdated?

CAPT HEWETT: That would be the ICNIRP standards that have been updated since 1985, which was the last time we published the rule. So obviously, the AELs in the '85 standard are not up to date.

DR. FARAONE: And also talking about standards, on page 7 you mention references to ICNIRP and ANSI limits. I was wondering if, between then, whether they are harmonized or they are complementary.

CAPT HEWETT: They're complementary?

DR. FARAONE: Yeah.

CAPT HEWETT: I would say they are. I think the ANSI derived their MPEs from the ICNIRP standard as it was updated, and they were both updated approximately at the same time. The IEC standard gives the person who's using the standard the option of using the IEC MPEs or the MPEs of their country's standards body. So our attitude is that we will adopt the ANSI MPEs.

DR. FARAONE: Thank you.

DR. McCOLLOUGH: I have several specific questions and first a comment. I thought these seemed very thorough and very well thought out, and your explanations very good. Will there be a further comment period of the re-proposal?

CAPT HEWETT: Yes.

DR. McCOLLOUGH: Okay. Does the FDA have active and meaningful membership on the IEC standard committees that you are --

CAPT HEWETT: Yes, ma'am.

DR. McCOLLOUGH: -- harmonizing with? Okay. How will the FDA keep up to date when these regs become out of date or obsolete, or have you thought forward that as IEC changes, these will follow?

CAPT HEWETT: Yes, ma'am, these regulations will become out of date at some point.

DR. McCOLLOUGH: Okay. So I know you're going to talk about the classes in the next presentation, but will existing laser products have to convert, or will we live in a dual classification system for a while?

CAPT HEWETT: There will be a grandfather.

DR. McCOLLOUGH: Okay. And the last one, which I think is going to come up a fair amount both today and tomorrow, are the relevant IEC standards widely available to the community? And specifically, I'm thinking about health and safety professionals at academic centers, other businesses, industry, etc., but may not -- I'm familiar with the IEC. I serve on several IEC activities. You have to buy these, and they're expensive.

CAPT HEWETT: Yes.

DR. McCOLLOUGH: And you buy this one, and it references 10 other ones.

CAPT HEWETT: Correct.

DR. McCOLLOUGH: And for the safety officer in a medical facility, that becomes prohibitively expensive to try to keep up with the IEC regulations. And so one of the things I'm worried about is the ability of the protection community to know what it is they're supposed to do and be testing and keep up with IEC when the documents are so difficult to obtain, as opposed to going to the *Federal Register* and the C.F.R. and have everything laid out for us.

CAPT HEWETT: As I understand it, one of the mandates in the federal government is to move toward consensus standards, and I think that's just across the board; that's not specific to this laser regulation. I just think that's the way forward, especially as we have international markets where the U.S. has to compete and send their products abroad. Products manufactured abroad have to come into the United States. We're kind of evolving toward everyone having to get the standard and buy the standards, but I don't know how else to address that question.

DR. McCOLLOUGH: Will the FDA be in some way giving user guidance documents that give the applicable performance standards, in a sense rewriting a cohesive document, that this is what it is in the U.S., even though a lot of that language comes from IEC?

CAPT HEWETT: I don't see any reason why not. We can paraphrase. For copyright reasons, of course, we cannot reproduce.

DR. McCOLLOUGH: But I think the user community in the U.S. needs something that's accessible to them that outlines the necessary steps.

CAPT HEWETT: You know, for a standard this complicated -- and I don't see how you could get away without buying it, honestly. If you're a manufacturer of these products, that is, you're in a business of doing so, then I think that's going to be your cost of doing business, is to buy these standards.

DR. MILLER: Donald Miller.

Let me just amplify a little bit. If an IEC standard is incorporated by reference in a regulation, it is possible to have that standard available on an ANSI website, which specifically includes standards that are incorporated by reference in federal law and federal regulations. That website makes it available to anybody for free, with some restrictions. You can view the standards, but you can't copy it, print it, download it, or save it, but it does make it available. So if, in fact, an IEC standard is incorporated by reference in a regulation, that is at least possible.

DR. LOTZ: Okay.

DR. IRWIN: Yeah, I'm glad I yielded to Cynthia because you expressed several of the same concerns that I have. And I think FDA needs to look at the whole user community to provide some means whereby the adoption of IEC standards allows state regulators who are looking at the aftermarket or the products after they've been introduced into the market, and maybe years, many years after they've been introduced into the market, and that other entities have the ability to look at this guidance. And so I'm glad to hear that FDA is looking at a way to do this.

But this posture that IEC standards are going to be adopted by reference really needs a serious look at how the safety community can know what is being said in those standards. Without it, we're undermining the linchpin of safety after products come into the marketplace and are used by humans for significant periods of time.

DR. MILLER: Donald Miller.

We are well aware of the concerns of state radiation regulators and the medical physics community and others who need to use these standards. We are actively considering a variety of ways to make these IEC standards more readily available than they are now, and the mechanism is not yet clear, but we are working on it, and we are aware of the issues involved, okay?

DR. IRWIN: Thank you.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: First of all -- Patrick Murphy -- I want to thank you.

Of the laser standards, it does appear that you've looked at the IEC and kind of picked and chosen for good reasons. You know, we'll take this from IEC but not this. So I don't know about some of the other standards where you just incorporate IEC at all, but I really appreciate the kind of picking and choosing that you guys have done.

I did have a question about these re-proposed amendments and our purpose today. Based on comments that we say, could that change what the amendments might be before they're put out in the *Federal Register,* or are we just another comment group, and the amendments are already kind of set in stone?

CAPT HEWETT: The re-proposal is not set in stone at all. It's just a draft document internally.

DR. LOTZ: Dr. Stein.

DR. STEIN: Toni Stein.

IEEE C95.1-2005 is a similar instance where they opened it up, and it was through dialogue and negotiations with them because it's used in FCC regulations. So that's a good example that you could point to is IEEE C95.1-2005. If you go online, you can download those for free to anybody.

My question is IEC as well as ICNIRP, since you participated or someone from your organization did, what do you think the makeup is? Is it all industry? Is it all industry and government? Well, how does it play out in terms of public health and safety representation?

CAPT HEWETT: That's above my pay grade, ma'am.

DR. STEIN: Okay.

CAPT HEWETT: I don't think I know.

DR. STEIN: And the reason I mention it to our group is because, like with code, electric code, any C code, it's the National Fire Protection Agency. Their interest is to avoid fires and shock and hazard, right? You know, they have a vested interest to protect people. And I'm just curious. In this IEC, I think of always the lighting industry, right? And I'm curious. I think we should do some background on that.

CAPT HEWETT: Do either of you know the makeup of ICNIRP or --

DR. LOTZ: We may have a Panel member who can speak to that a little bit.

CAPT HEWETT: Oh, you can. Yeah, of course Bob can.

MR. ALDRICH: ICNIRP not as much as I can speak to IEC. IEC has membership from various manufacturers, organizations, regulators, and most pronouncedly, test houses. It's been my personal experience that much of the work that happens in IEC committees is consensus to make sure that -- and I'll say this bluntly, job security is one of the variables that I find is sometimes brought up in some of those meetings.

DR. LOTZ: All right, let's -- okay, one question from Dr. Irwin.

DR. IRWIN: I've read a lot of ICNIRP, and I can state, from my perspective, that's a more balanced group of scientists, typically academia and public health organizations, with some balanced industry perspectives. But I agree with your point, Dr. Stein, and it's useful to ensure -- and I would reinforce that that makes for the states -- and I, of course, represent a state -- that FDA either cherishes their position as a channel to state regulators, who do try to provide for safety after devices are sold and also represents as jealously as they can states' interest, and it could be advisable for FDA to even consider funding some state representatives to attend IEC or to be a part of IEC so that there is a broader perspective from our radiological safety community. And it takes some of the burden off of FDA, let alone the fact that it expands the nature and types of people that are engaged from the regulating community.

DR. LOTZ: All right, let's move on to the next presentation, then. Captain Hewett is Round 2.

CAPT HEWETT: Okay, this next presentation is more specifically targeting those elements that I mentioned previously that were being re-proposed. Or actually, these are going to be proposed for the first time. They were not initially in the 2013 proposed rule, so they're not technically re-proposed. So these are laser LiDAR products, which is light distance and ranging, and remotely controlled mobile laser products, and laser pointers.

So as promised, I'm going to go through some laser hazard classifications. I think all of you probably are familiar with these, after all, but I'll just say that the FDA has the Roman numeral classification system on the left, and the Arabic numbers are the IEC classifications on the right, and you can see where these match up in terms of hazard class, going from the least hazardous from the top down to the most hazardous at the bottom of the table.

So you see that C, M, R, B are classes that we haven't had before, and they're going to be adopted. Or actually the 3B and 4 were a direct correlation to our own IIIb and IV. So enough about hazard classification.  Let's go toward the reason why we're looking at these three types of laser products in the first place.

We feel that laser emissions are increasingly encountered outdoors and in the home, as opposed to academic or work environments where they typically have been found when the laser rule was first promulgated.  So in the future, we think exposures to laser light radiation will be as commonplace as exposure to electromagnetic radiation, let's say, from communication systems like cell phones.  Laser products are intentionally or collaterally exposing people to invisible laser radiation so that laser radiation exposures are generally not noticeable.

So let's look at LiDAR.  As I said, LiDAR is light distance, or you could say detection, and ranging.  These are laser products used for distance, for detection, or ranging measurements, and they generate a range-based dataset in one, two, or three dimensions.  During operation, some of these products may intentionally or unintentionally expose people to hazardous levels of laser radiation.

Now, you can see as an illustration you could have an airborne platform.  You could have a scanning system that scans the human body for facial recognition or gesture recognition.  You could have robotic systems that emit laser LiDAR signal for just being able to detect objects, and as well as the airborne platforms for the drones that are fairly emergent at this point.

So we believe these are LiDAR products or specific-purpose laser products for some time.  Specific-purpose laser products have certain surveying, leveling, or alignment uses.  And they do have a class limit in 1040.11(b).  They're limited to no higher than Class IIIa or the CDRH recognized equivalent, the IEC Class 3R.  However, LiDAR products are not considered specific-purpose laser products at this time by FDA, and as a basis for that decision, we look at the preamble at 39 Federal Register.

Back in '74 a question was posed. You know, are you going to put LiDAR, or light distance and ranging, products into the SLA category and therefore have a class limit? And we said, or at least the Commissioner at the time said, "The imposition of the requirements (i.e., a class limit) of 1040.11(b) on distance measurement laser products is not appropriate since substantially higher powers and different beam configurations are required for ranging purposes." So CDRH interprets this as specific to LiDAR applications.

Some concerns about LiDAR. There's no class limit for LiDAR products, as I just stated. There is potential for exposure to the emission. When these products enter the marketplace, there's no premarket safety review. There is a difficulty in detecting or associating injuries with the product due to their invisible emissions, and manufacturers may instruct the LiDAR operator to terminate the emission under unsafe conditions. This is an administrative control and is not reliable.

So what do we want to do? We want to propose an amendment to the performance standard for LiDAR products to lessen the hazard from anticipated exposures to 1M, 2M, IIIb, or IV class emissions.

We propose that LiDAR products integrate as many interlocks as are necessary for the safe operation during the intended uses. And these interlocks shall limit exposure to no greater than Class IIIa or 3R accessible emissions.

We propose that specific LiDAR products ,such as rangefinders and speed detectors, shall not be in Class 1M or 2M and shall be limited to no higher than Class IIIa or 3R. Of course, we have a variance process in place for products that exceed Class 1 or are in Class 1M or 2M or IIIa or 3R.

What is your opinion of FDA's LiDAR safety concern where we are looking at everything I just mentioned as a potential safety issue? And what is your opinion of the Class IIIa/3R limit?

MR. ALDRICH: Yeah, Robert Aldrich. Can you hear me? Okay.

Class 1M and Class 2M lasers can, under certain circumstances, not exceed the Class 3R exposure limits. I've seen this ever since Class 1M and 2M were generated by IEC some years ago. This has been one of my most commonly referenced concerns that I have about that. For anybody that is unaware of what these classes mean, I'll give you the super-CliffsNotes version.

For unaided exposure condition, the class limit is -- if it's not exceeded for Class 1, would be a Class 1 laser. If it could exceed the Class 1 limit for aided viewing but not for unaided viewing, that would qualify it as a Class 1M. However, it only needs to exceed that Class 1 limit by the smallest margin. If you were to be two times the Class 1 limit for aided viewing and not exceed it for unaided viewing, that would by definition be a Class 1M laser that does not exceed the Class 3R limit. So if you were to perform a hazard evaluation, you would find that it's a Class 1M laser with no hazard distances.

So it's been a concern that I have when we see in any kind of a document that requires specific class lasers, to exclude a Class 1M or a Class 2M laser as being considerably -- or suggest that it's more hazardous than a Class 3R. This I see as a hole in this, and it's not unique to this. I see this all over the place.

I do understand your second bullet under the question of what is your opinion of the Class 3R limit being the limit, but to exclude Class 1M and 2M is problematic in that regard. The way of making a laser 1M from a safety point of view is a positive because it would suggest that you're enlarging the beam, so less of the pulse energy or the power from the laser would enter an eye and therefore be less hazardous than if it was a smaller beam. So I'm concerned that this modification would, in fact, be de-incentivizing making a safer system to comply with the standard. So that's one of the issues. I'm sure you follow what I mean.

CAPT HEWETT: Noted.

MR. ALDRICH: We've talked on this before.

CAPT HEWETT: Absolutely. Thank you. Any other --

DR. LOTZ: Dr. Irwin.

DR. IRWIN: I'm trying to understand the classes, and I followed your discussion there, and it's very useful, but one of the things I always kind of relied on relative to the classifications is either the blink reflex for visible wavelengths or quarter-second exposure time for invisible wavelengths. And can you describe for me how that kind of protection factors into these new IEC standards, and if you feel that the outdoor use is sufficiently protected by these new classifications based on --

CAPT HEWETT: Well, I don't think the outdoor use has anything to do with it, but it certainly does increase the potential for exposure to the public who would be looking at one of these products directly, reasonably assured that they would look directly for longer than a quarter-second. Maybe 10 seconds, maybe a minute, you know. So some of these products scan, and they're in an aerial platform, and exposure would be incidental, and it wouldn't be a concern. But we're saying because there are interlocks that are required for the intended use, that if you're in an aerial platform, the product is not going to be an exposure risk, right? So you would put certain interlocks in place to keep people on the ground safe. Let's say a weight-on-wheels interlock for an aerial platform or an altitude interlock for an aerial platform. That would bring the exposure down to Class 1 levels or at least no higher than Class 3R.

DR. IRWIN: And then for drones, I have to tell you, just going to Best Buy with my son the other day and seeing how many there are now with laser devices, has the FCC weighed in on this and made sure that there are -- not FCC -- FAA. I'm sorry, they're the ones that regulate drones. Are you cooperating with them to make sure that these people that buy drones are operating them in a safe manner, as well as what you're trying to do with the laser?

DR. LOTZ: Pardon my interruption, but isn't that your next presentation?

CAPT HEWETT: I didn't address the FAA aspect.

DR. LOTZ: Okay.

CAPT HEWETT: So I'll address that now. We do work with the FAA. The FAA has their own form of guidance, and they address the use of LiDAR products on aerial platforms, and they actually approve those LiDAR products for specific aerial platforms, and I don't see why drones would be any different.

DR. IRWIN: Okay, thank you.

DR. LOTZ: I'm thinking maybe we ought to let Captain Hewett go on --

CAPT HEWETT: Okay.

DR. LOTZ: -- since there's some overlap here with the other presentations and then come back with questions.

CAPT HEWETT: Okay. So I had other questions there, so we can address the discussion point, your opinion on 1M and 2M and rangefinders and speed detectors. I mean, in other words, are these limits appropriate?

DR. LOTZ: We will come back to those in the discussion period.

CAPT HEWETT: Okay. All right. So now we're going to move on to remotely controlled mobile laser products. So these are -- you know, they require remote operational control of the emission, and they're mobile. So two basic examples right there, a robotic platform and a drone.

Our concern is the safety, again, of these potential public exposures to a laser emission that may require the operator to judge and maintain a safe distance between the mobile platform and the public. Again, these products have no premarket review, so they enter the market as designed. We believe that we would have difficulty detecting or associating any injuries with the product due to the invisible emissions. Manufacturers may also instruct the operators of these mobile platforms to terminate the emission during an unsafe condition, and that can be something in the user manual, let's say. And we're also concerned about loss of communication and control of the product. How is the product going to cut the emission in the event of a signal loss?

So the operator of an RCMLP is not required to have a controller-based means of beam attenuation. Currently the attenuator, in the regulation, shall be provided with "one or more" permanently attached means, but we want to make it more specific. Upon signal loss, the operator cannot monitor the beam attenuation, and without a manual reset, the product could emit laser radiation continuously or upon restart. So I'm thinking about the scenario where you've got a drone, it's emitting Class IIIb or IV radiation, and you're doing some surveillance work with it, some sort of navigation system cuts out, and the product crashes to the ground and still continues to emit Class IV radiation.

So what do we want to do? FDA wants RCMLPs to have a IIIa/3R class limit, and we want to exclude Classes 1M and 2M. Let me reread that. FDA wants RCMLPs to have a Class IIIa/Class 3R limit and wants to exclude Classes 1M and 2M, meaning these products would not emit 1M or 2M. Because the products attract attention, we believe that the 1M and 2M limit is an issue with these particular products because you're going to want to look at the product with viewing optics, like a binocular or a telescope or whatever.

So RCMLP emission indicator requirement: So currently under 21 C.F.R. 1040.10(f)(5) -- I'm paraphrasing here -- laser products such as RCMLP that have separately housed laser and operation control shall incorporate an emission indicator, if the laser or operation control can be operated at a separation distance greater than 2 meters, or from any other separately housed portion of the RCMLP incorporating an emission indicator.

We propose an amendment to the performance standard that requires the following: a beam attenuator on the RCMLP and a beam attenuator actuator on the operation control, regardless of separation distance. We consider the 2 m to be arbitrary, okay?

We also want an emission indicator on both the RCMLP and operation control -- oh, did I just say that -- regardless of separation distance. No, I didn't. So we have a beam attenuator and an emission indicator on basically both parts of the product, the control and the product itself that emits radiation.

And we also propose an amendment that the RCMLP must not permit human access to laser radiation in excess of the accessible emission limits of Class 3R upon loss of operation control, including signal, machine vision, or electronic guidance system failure.

We also propose to exclude Classes 1M and 2M, as I stated earlier, as the products will be likely viewed through viewing optics.

So our questions for TEPRSSC are for laser products designed to be remotely controlled, what's your opinion regarding the separation distance elimination, requiring an emission indicator on both the control and mobile product, requiring a beam attenuator on the actuator -- a beam attenuator actuator on the operation control that controls the beam attenuator on the mobile product?

And what's your opinion of the class limit?

And what is your opinion on the likelihood that RCMLPs will be observed using optics that increases the observer's risk of injury?

DR. LOTZ: I think I'm going to ask Captain Hewett to go on and do this other presentation, and then we'll have time for clarifying questions.

CAPT HEWETT: Okay. How much more time do I have?

DR. LOTZ: Actually, I think we're supposed to complete this whole section by

2 o'clock, including your colleagues' presentations.

CAPT HEWETT: Including the next presentations? Wow.

DR. LOTZ: Yeah.

CAPT HEWETT: Okay. Sorry, this went a little slower than I had planned because I didn't factor in questions. So we're going to go through as quick as possible.

We propose that we define a laser pointer. Laser pointers have not been defined yet in the regulation. We believe that they are handheld laser products designed for battery-powered operation that are manufactured, designed, intended or promoted to provide illumination, designation of a target or point of origin, or sighting, with no associated technological or scientific purpose for the laser's emission. So in other words, just because a product points and it looks like a laser pointer doesn't mean it's necessarily a laser pointer if you're using the emission for a purpose that has a technological use. So laser products are not excluded as laser pointers when used for visual entertainment, vision disruption, to startle, or novelty purposes. So that's just one part of this presentation is defining a laser pointer so everybody knows what one is.

But our specific concerns with laser pointers as they exist now are that they emit visible wavelengths in the 400 nm to less than 610 nm that are a significant safety hazard to operators of marine vessels, aircraft, and motor vehicles. Of course, according to the FAA, which has been tracking illuminations of aircraft, most illuminations occur at night by green lasers 88% of the time that are 28 times brighter than equivalently powered red laser pointers. These illuminations cause startle, distraction, glare, flash blindness, and a persistent afterimage of a reverse contrast shadow in the visual field, lasting minutes. This effect renders operators of aircraft particularly vulnerable since they rely heavily on reading instrument panels. Rotary wing aircraft that fly at low altitudes must also rely on night-adapted vision to identify airborne and ground-based hazards. Since 2006 there has been an 80-fold increase in reported incidents of aircraft illuminations from laser pointers, according to FDA analysis of FAA public data. FDA has received numerous letters from Congress requesting action on laser pointer illuminations of aircraft.

Due to recent technological advances, laser pointers with green or blue laser diode systems are now available. Previously, they had only emitted red light. It's well established that humans are more visually sensitive to green light, and humans are far more sensitive to green light at night. As a result, green laser pointers are a much more significant safety hazard than red laser pointers. Due to a 50 nm shift in color sensitivity toward blue wavelengths and away from red wavelengths at night, blue light appears to be much, much brighter than red light at comparable power outputs.

To illustrate this point, let's take a look at this graph. What we are looking at is luminous efficiency versus wavelength, and you see there are two curves. One is a photopic vision curve, and the dotted line is the scotopic vision curve or dark-adapted vision. Let's take, for instance, you see just above 600 nm in wavelength, there's a red bar, and that signifies the red laser pointer, and you'll see where that red laser pointer intersects the scotopic vision curve at a very low point, okay? So you're not very affected by a red laser pointer at night at all, but you're somewhat more affected by or can see it better during the day.

And you see how this curve interaction shifts over into the green wavelength. You're much more sensitive at night. You can see where that bar went all the way up much, much higher than the red. And even during the day, you're more sensitive to green.

And then, as scotopic vision takes over for the blue, again, during the day you're very, very unlikely to be affected by a blue laser pointer, but at night, you see it even exceeds the red. So the green and the red [sic] laser pointers are affecting people quite significantly at night.

So the hazard from flash blinding is significantly reduced when laser pointers emit in the red/orange wavelengths of 615 nm or longer. The hazard from laser aircraft illuminations would be effectively eliminated if green and blue laser pointers were not available. Colors at 615 nm and longer, viewed with night-adapted vision, appear only 1.4% as bright as green at the commonly manufactured 532.

So we're basically saying at FDA, leveraging 21 C.F.R. 1003, that the pointers are defective. So our defect regulation states the following: Electronic products shall be considered to have a defect which relates to the safety of use by reason of the emission of radiation if -- and I'm paraphrasing -- it's a product which utilizes electronic radiation to accomplish its primary mission or primary purpose and from which such emissions are intended, and without regard to the design spec of the product, it emits electronic product radiation unnecessary to the accomplishment of its primary purpose, which creates a risk of injury.

So what do we want to do? We want to amend the performance standard to require that laser pointer products must not emit laser radiation in the visible wavelengths from 400 to 610.

What do you think of this definition for laser pointers, and what's your opinion regarding that startle and flash-blinding hazard exists as a problem when laser pointers are only available in the red wavelengths?

Does startle and flash-blinding hazards with green and blue laser pointers justify calling them defective, and what is your opinion regarding the exclusion of wavelengths from 400 to 610, specifically those wavelengths for laser pointers?

DR. LOTZ: Thank you, Captain Hewett.

So the questions he's posed to us, we can actually leave for the discussion period later. So now would be the time to ask questions of him to clarify what he's got in there, not to deal so much with the discussion.

Go ahead.

MR. ALDRICH: Could you clarify what you just said?

DR. LOTZ: So he's posing questions to TEPRSSC which we'll have a discussion period for later. So right now, what we want to do is just ask him clarifying questions of his presentation without going into the depth of those questions.

CAPT HEWETT: Is there anything you didn't understand?

MR. ALDRICH: I can ask him questions, but not about what he said?

CAPT HEWETT: Was anything unclear in the presentation that I should cover before you go into deliberations?

DR. LOTZ: Yeah, if you need to clarify that he's confused something or it's not clearly stated, go ahead and ask that now. But if we want to wrestle with the questions that he's posing at the end of his talk, let's leave that for the discussion period.

MR. ALDRICH: Okay. Well, then I'll have to -- I disagree. I think it's drawing a perspective that isn't -- I disagree with --

DR. LOTZ: I think that's perfectly appropriate for our discussion period, but let's leave that for that time.

Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

These classifications are new to me. I'm not with the laser safety background, but it may just be semantics and the wording, but Class IIIa and 3R say avoid exposure to the beam. That seems like that wording would apply to me as the potential person getting the laser in my eye, that I should avoid it. And it seems that the classification from the FDA point of view is the manufacturer should use the phrase "avoid exposing someone." I'm thinking of like a speed detector. I would love it if I could avoid exposure to a speed detector.

CAPT HEWETT: I believe the labeling is intended for the operator. So the operator has been warned by the labeling to avoid exposing someone to the direct emission.

DR. McCOLLOUGH: Okay, that's the word that's missing. You're meaning avoid exposing people or animals --

CAPT HEWETT: Yeah.

DR. McCOLLOUGH: -- as opposed to avoid exposure for myself.

CAPT HEWETT: They probably shortened the phrase for a practical matter for label size. I don't know what was the rationale, but I agree that it could be phrased better. But it's in the regulation, and it's in the standard.

DR. McCOLLOUGH: But it's avoid exposing someone, something?

CAPT HEWETT: Yeah.

DR. McCOLLOUGH: Okay.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

In your revised proposed amendment subsection, you mention the interest in adopting all of IEC's up-to-date accessible emission limits. And yet, the classification of lasers is not totally consistent between FDA and IEC. How can you ensure that you use up-to-date emission limits from IEC when the FDA classification of lasers is not totally consistent with IEC's? How do you envision doing that?

CAPT HEWETT: Those classifications will go away, the CDRH classification system will go away.

MR. KEITH: So you'll adopt --

CAPT HEWETT: Yes.

MR. KEITH: -- the IEC's?

CAPT HEWETT: That's correct.

MR. KEITH: And when IEC puts out another publication and provides a different guidance value, will there be a period of time in which U.S. manufacturers or imports into the U.S. would have to comply with the new guidance or new requirements?

CAPT HEWETT: Yeah, I believe there's a 2-year period before the limits are completely adopted, in effect in the laser rule.

DR. LAMBETH: Dave Lambeth.

So I come back to the pointer question, the definition, a little bit. So your Slide 33, simply they designate all blue and green pointers as defective.

CAPT HEWETT: Yes.

DR. LAMBETH: What does that practically mean to be designated?

CAPT HEWETT: Practically, for FDA, it means that we wouldn't be able to send out a bunch of people from FDA, taking green and blue laser pointers off the shelves or off the market. We don't have that --

DR. LAMBETH: So does it mean I would not be able to buy a green laser pointer?

CAPT HEWETT: Manufacturers would be prohibited from manufacturing laser pointers in those particular wavelengths.

DR. LAMBETH: So it doesn't matter what the power level is, it's just green?

CAPT HEWETT: That's right; we would consider those to be defective. However, as a practical matter, we envision that just like any other hazardous product that has been determined to be defective, that state and local laws -- ordinances and laws would be put in place that would likely deal with the use of green and blue laser pointers.

DR. LAMBETH: So as a manufacturer I could still sell it, but then effectively, I would be liable.

CAPT HEWETT: As a manufacturer, you would not be able to enter into commerce with a product that we believe is defective, and you'd be violating the regulation to manufacture a laser pointer in those wavelengths, but you could get a variance from FDA. Let's say you had a good reason to have a green laser pointer for sighting purposes, the FDA could grant a variance for a specific use.

DR. LAMBETH: So as a professor and lecturing all the time and giving talks and whatnot, I commonly used a green pointer laser --

CAPT HEWETT: Right.

DR. LAMBETH: -- but simply because it's easier to track on the screen. As you point out, it's easier to see, okay?

CAPT HEWETT: Yes.

DR. LAMBETH: But in point of fact, the power output of that laser, okay, is miniscule compared to the power output that I can buy that falls out of your wavelength restrictions today. I can go buy a 650, which admittedly is not as sensitive to the eye.

CAPT HEWETT: All laser pointers --

DR. LAMBETH: But I can buy it at 20 times more power out of it than I could the green laser at one-third the cost.

CAPT HEWETT: All laser pointers would still be class limited to Class IIIa as specific-purpose laser products. They would have a Class IIIa/Class 3R limit.

DR. LAMBETH: So blue wouldn't be defective if I lower the energy level?

CAPT HEWETT: That's not true. You know, the fact is, is that laser pointers in blue and green, even whenever they are in Class IIIa/Class 3R, can still cause the same startle --

DR. LAMBETH: Um-hum.

CAPT HEWETT: -- a flash-blinding effect that we're trying to guard the public against.

DR. LAMBETH: So just for your reference, and I was telling one of my colleagues before the meeting started, that I recently purchased 650 nm red lasers.

CAPT HEWETT: A red laser.

DR. LAMBETH: Okay, from China admittedly.

CAPT HEWETT: Yeah.

DR. LAMBETH: Okay, $10. They put out 200 mW of power.

CAPT HEWETT: That's a different question. I mean, that's an import issue.

DR. LAMBETH: I understand it's totally different, but it came in a package with the simple leads that came out, and they supplied a battery pack for AAA batteries so I could use it as a pointer.

CAPT HEWETT: Absolutely.

DR. LAMBETH: Yeah.

CAPT HEWETT: But we have literally thousands of products on import alert at the FDA, and when you're dealing with internet commerce from foreign countries, there's a limited amount of things that FDA can do when products are drop-shipped to your home from another country.

DR. LOTZ: Dr. Stein, you had a question?

DR. STEIN: Drop-shipped using a laser pointer. So my question is clarification on "no higher than." What if there is -- I mean, are you serious that these products -- what if they're worse than -- they can't get a higher rating? What if they're even worse? That's what I don't understand, "no higher than," why you're limiting it to the product. It says in the sentence -- this is on page 6, or 12, in your Slide 12. That's one question. The other question is --

CAPT HEWETT: Could you go back, because I'm confused.

DR. STEIN: Sure.

CAPT HEWETT: What were you referring to?

DR. STEIN: It's on your Slide 12. You say limited to no higher than. I would think it would say that the LiDAR product can't be -- you know, it has to be lower than. So I'm not clear on that.

CAPT HEWETT: The way the classification works is the lowest classes are safer.

DR. STEIN: Yeah.

CAPT HEWETT: So we say you're going to limit the highest class to IIIa/3R.

DR. STEIN: Oh, that you can sell that to.

CAPT HEWETT: Right.

DR. STEIN: Okay, I get it. Thank you. And then the last thing is novelty purposes. For scope, were you referring like novelty purposes -- this is Slide 26. Could that be like for music events where they have laser shows? Is that a novelty event? What do you mean by novelty purposes?

CAPT HEWETT: You know, a lot of laser pointers are used for busting balloons, and they're basically used as toys. I mean, you can use them to play with your cat.

DR. STEIN: Okay. But lasers for shows, is that included here or no?

CAPT HEWETT: That would be a demonstration laser product, which we have separately regulated --

DR. STEIN: Okay.

CAPT HEWETT: -- under the demonstration laser product definition.

DR. STEIN: Thank you.

MR. ALDRICH: Yes, Robert Aldrich.

When laser pointers first became available cheaply on the market, they were red. Red laser pointers were very inexpensive to make, a little diode and all of that. When the transition to green occurred, the reason for that -- because they were more expensive. The reason that people would prefer a green one over a red one was that it appeared to be brighter, and it was able to do a higher, brighter image without having to increase the power. And at the time it was, rightfully so, argued that it was safer because you could get more brightness without having to increase the power of the laser. I appreciate and I understand why it has now become more of an issue for outdoor applications regarding aircraft safety and that sort of thing because it creates -- with being brighter, it can create a visual stimulus that can be distracting, disorienting, even create flash blindness, etc. But I'm extremely concerned about this because the purpose -- specifically about referring to it as being defective, because the purpose of having a laser pointer is to be able to see what it is pointing at.

So the visual stimulus that you're trying to achieve by requiring it be in the red, where you can't see it as well, requires an increase of power to create the same visual stimulus. So as I see this, what we're doing is we're making a decision to reduce the effects and possible hazards of a temporary effect such as disrupting a person's vision temporarily, a flash-blindness effect, by increasing the hazard of permanent damage because you would be increasing power to have the same stimulus effect. I don't understand how it could be argued that it is a defect in order to have the same visual stimulus effect at a safer, from a biological tissue interaction point of view, limit.

So it's very concerning to me to suggest that you need to preclude lasers that are pointers that point well because of a possible misuse of those devices. I think that that increases hazards from biological damage, for the same reason that they came up with the green lasers to begin with. So that's my concern.

And I think that there are specific applications for which -- essentially without a variance, you would not be able to have the ability to use a laser as a pointer in daylight if this prohibition were there. You cannot see 5 mW of a red laser, for example, in an outdoor environment for lining up a level, for example, when trying to build a shed in your backyard. You wouldn't be able to do those applications anymore, where you might be able to do that with a green one.

CAPT HEWETT: That's good points.

MR. ALDRICH: It's the trades space.

DR. LOTZ: And I think these are all things that we need to discuss more. So in the interest of time, I think what I'd like to do is move on to the other two presentations we have in this section, and then we'll come back to these issues when we get to that point. So let's turn to Dr. Howard for his presentation on Lamps for General Illumination and LIPs.

DR. HOWARD: I'll be as quick as possible. The questions for the Panel are a little less weighty, and I want to make sure that Dr. Calhoun gets his full measure of time, and I'm sure you're going to have lots of questions for him as well.

So laser lamps. I'm Lowell Howard. You know me from this morning. Laser lamps are a type of solid-state lighting and can be looked at somewhat similar to LEDs. If you've been into a hardware store lately and wandered around the lighting aisle, if you're not technically inclined, you're probably confused by things like color temperature, and there's a lot of numbers on these products. And basically, in a nutshell, the difference between laser lamps and LEDs are laser lamps are useful for the very brightest -- replacing the very brightest xenon and halogen lamps that are in use today. Some of these lamps are used in high-bay warehouse lighting, projector lamps, spotlights, stadium lighting, and car headlights.

And currently they're the subject -- have been the subject of a lot of U.S. Government investment in research and development, namely the Department of Energy, because they promise greatly reduced energy consumption as well as much longer lamp lifetimes, which leads to fewer ladder accidents obviously because fewer people have to go up on ladders to replace lights in high bays. It should be fairly obvious that it's a good benefit from a safety standpoint.

Another one: When I was looking in the Consumer Product Safety Commission's database of injuries, injury reports from 2015, there were, I think, about 20 injuries reported just in their small sample of ER visits for broken lamp glass, eye injuries just from people changing light bulbs, either a CFL or an incandescent. The glass envelope had broken, and they had a direct eye injury from glass. And so as long as you don't incorporate glass into your solid-state lighting, you will avoid that one as well. And finally, as a benefit, new lighting formats and aesthetics for public spaces.

So a laser lamp: A blue laser, typically 445 nm, will remotely pump white phosphor. I say remotely pump because in an LED, typically this phosphor is directly located on the LED substrate. By doing so remotely, one of the advantages of a laser, you can use collimated beams, you can use fiber delivery systems, and you also remove the heat source, the thermal heat from the blue light that energizes the phosphor, and this can lead to longer lifetime and higher efficiencies for the phosphors.

Another type of lighting that has only seen very limited application thus far directly combines three or four either tri- or tetrachromic lasers to produce white light directly without the use a phosphor, and that increases efficiency about another 10%. So these are the highest efficiency lamps you could imagine. There's no phosphor to wear out at all. And so you could see lifetimes of 100,000 hours or more, just depending on how long you can make the lasers last. It's also a little bit easier because all the sources are laser based. It's easier to get these light sources into a network of optical fibers and then mix them together. So things like endoscopes and illuminators for surgical procedures could benefit from their use and adoption.

So now that we've talked about benefits, let's get into risks. Obviously, it's a laser, and it's got a protective housing. We're talking about blue 445 nm laser diodes. Anywhere between half a watt to 20 or 40 W of laser light, you don't want to have a protective housing failure, and that's why these are regulated as lasers.

Another part of the laser regulations that are important are component lifetime aging. Sometimes there's diffusers in the phosphor itself. If the phosphor ages -- as the phosphor ages, it will produce less of the white part of the light, and you'll get more blue. And so the color mix will change over time, and it will become more blue and perceived to be a little bit more harsh. In the regulations there's clause 1002.10(h). That refers to reporting of component lifetime aging, and there are requirements for manufacturers so that they do a good job with that and report it to us. If there's any concerns on that, that's covered adequately in the regulations.

Some scientists have concerns about the -- Reidenbach in Austria has done 15 years of research on the reliability of the human aversion responses to bright lights. That's relevant here because these are some of the very brightest lights that you will encounter in typical day-to-day use, things like, if you can imagine, everybody can relate to driving down a dark road at night, and all of a sudden here comes somebody with bright headlights, and you turn away. You can't avoid that. That's an aversion response beyond just pupil dilation. So that's one area.

And the reason there's a concern is there's an assumption in the laser industry that a quarter-second, and you will blink. Well, Reidenbach did a series of researches and discovered that, well, this assumption that a lot of things are based upon in laser safety, only about 29% of the population actually had the blink response that everyone expected to be there in that way. So it appeared to be also somewhat based on the number of photoreceptors that were eliminated. So lasers would be generating a smaller response because it's a smaller spot size on the retina. Laser lamps should generate a larger response, and it may not be an issue, but I'm just listing it here as a concern.

Also in the LED space -- I've seen many newspaper articles lately, and the American

Medical Association has made some recommendations, and these are in the briefing materials -- blue light disruption. Researchers are reporting issues with sleeping. I'm not a bioeffects expert. Dr. Sharon Miller is our ICNIRP representative. She's in Beijing right now at an IEC meeting. So if you have questions on that, I would respectfully ask to -- I can relay those to Dr. Miller because I'm not an expert in that field.

So laser-illuminated projectors: These are a product that's been on the market for, oh, a good 5 -- at least 5 years now, and this is an example of where bright halogen lamps have been replaced with lasers, and quite successfully, I may add. Hybrid lamps will combine sometimes a red LED with a blue laser that strikes a phosphor to produce the proper color temperature so that movies and TV are reproduced in the proper color fidelity, and that's something very important for the entertainment industry. So any issues that would exist in lamps with it being excessively blue would not exist in the laser-illuminated projector space because color fidelity is very important to them. They have a vested interest in reproducing colors in a very fixed way, according to industry standards.

In the very brightest of laser-illuminated projectors, as is true of theater projectors, there does exist an ocular hazard zone in the zone of right in front of the projector. Theater projectors are protected by a piece of glass up on the projection booth, and that's called Risk Group 3, and there is some risk of a thermal injury. That's an engineering control by putting it in the theater that way, and the engineering controls have been very successful. I think a recent paper by David Sliney cited only one case of an injury over, you know, however long theater projectors have been in use. It's coming up on 100 years now or something. I think there was just one injury in the Soviet Union back in the 1940s or something like that. So the engineering controls have worked quite well.

So CDRH issued LIPs guidance in February of 2015, and LIPs are -- the IEC, we're bringing in yet another IEC standard, IEC 62471, which probably people may not be familiar with. It's a lamp standard, and this brings the risk group classification. You can think of Risk Group 3 as roughly equivalent to Laser Class 3B and 4, as in there are some hazards of burns and things. Risk Group 2 and lower would be similar to 3R and down.

So what we're looking at is Risk Group 3 projectors have been available by variance for theaters. There are good reasons for putting Risk Group 3 LIPs into use in spaces. Like if this room were a little bit larger, you might benefit from having a Risk Group 3 laser projector hanging off the ceiling on a mount, projecting a beautiful image of a black and white slide. We'd probably have a nice brilliant blue FDA logo in the corner. What we'd like to do is get out of the variance business because that's really an administrative control. We like engineering controls. We'd like to explore engineering controls for -- this is poorly worded -- fixed and non-fixed. What we really mean there is non-theater applications. And so we'd like to give people an option.

Variances will still exist, but we'd like to move things in the direction of having a virtual protective housing, as we've done on several variances, where if there's a risk zone in front of a lens, some type of sensor monitors the risk zone. We don't want to say what kind of sensor and we don't want to tell industry how to do it, but if you put in a safe and effective engineering control that will dim the projector, and these are part of some of the industry standards that are out there right now, you can do that and put a Risk Group 3 projector into places that you can't now without a variance, so things like a projector on a tabletop that's at eye height or a cart as they're typically used in hotels. Right now, that would require a variance that we -- I don't know if we have any variances for Risk Group 3's on carts. This would be an enabling feature of the regulations if we can get the engineering controls into them.

And we're also looking at -- there's a precedent -- type T mercury vapor lamps that have engineering controls to protect against protective housing failures which expose -- you don't see these lamps quite as much anymore, but they could expose you to harmful ultraviolet radiation, like in a school gymnasium. Imagine a basketball would go up and break a lamp envelope; type T mercury vapor lamps would self-extinguish. And if something like a car headlight has a 20 W Class 4 blue laser inside, you'd like to know if the protective housing has failed so that you're not leaking blue laser light onto an accident scene. A reasonably foreseeable failure would be an auto accident, broken glass, broken headlamps. You see this all the time. We would like to -- we are contemplating, and we would like to see some type of engineering control that would detect the failure and make sure the lamp is shut down so first responders don't have to deal with that on top of all the other things they have to deal with at an accident scene.

So our questions are related to what do you think about the virtual protective housing approach? I think optical component failures are hopefully adequately addressed on the existing regulations. We want to know what you think about that.

And what is the best way forward to assure the safety of things like laser lamps in car headlights? Combinations of existing standards or do we need to modify the performance standard?

And there we go with the virtual protective housing.

I am going to move on. Let's see, Dr. Calhoun is -- and if you have questions now for clarification, I'll take them. And if not, we'll move on to Dr. Calhoun.

DR. LOTZ: All right, we'll go with a couple of quick questions.

DR. FARAONE: Yes, thank you. Antonio Faraone.

Really quick, you mentioned virtual protective housing. I don't know what that is.

DR. HOWARD: Okay, it would be engineering -- okay, protective housing has, in the regulations, meant basically a box around the laser. If there's a hazard zone, a hazardous zone in front of the projector lens, say, in a theater application, it's in a locked projection room with a piece of glass that protects that Risk Group 3 hazard zone. That's a simple engineering control, if you will.

A virtual protective housing would be something that would -- it's a bit of a buzzword, but it would be an engineering control that would monitor that space just like an ultrasonic sensor on the back of your car that tells you, hey, there's a kid on a bicycle right behind my car. It would monitor that space. I don't want to say how to do it, but it would monitor that hazard zone and dim the projector output down below to Risk Group 2 or lower so there would be no hazard. And the case in point would be like a projector right behind you that's on a cart. Is it eye level for a child? And that's one of our deepest concerns.

DR. FARAONE: Thank you.

DR. LOTZ: Dr. Stein.

DR. STEIN: Toni Stein.

What about square wave? These are all constant DC wave or other square wave?

DR. HOWARD: Well, these are video projectors. I mean, video projectors send images, and images are signals.

DR. STEIN: Okay.

DR. HOWARD: And we look at movies -- we've been looking at movies for 100 years.

DR. STEIN: Right, right. And what about flicker issues?

DR. HOWARD: Movies flicker at, I believe, 24 Hz frames per second, which is more annoying than 60 frames per second of a video.

DR. STEIN: Um-hum. Okay.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

As part of the protective housing, you know, when you have a blue laser and it's hitting a phosphor and it's changing the color, is the phosphor also considered to be part of the protective housing since it prevents the blue light from coming through directly? And if so, is burn-through of the protective -- of the phosphor, would that also be considered to be a failure of the protective housing? And if so, how would that be evaluated and controlled?

DR. HOWARD: So in the case I've got here on Slide 6, in this case the white phosphor would be considered part of the protective housing. You could have a reflective system, though, where it's back-illuminated. Rather, this is back-illuminated. You could have a system where the laser illuminates like a Canon dioptric system, like a telescope, like a Cassegrain telescope, where the laser illuminates a spot of white phosphor, and it's pointed in the other direction, and then that is magnified out the front. So it doesn't have -- the phosphor doesn't have to be part of the protective housing.

MR. KEITH: But if the blue laser essentially burns through the phosphor such that the blue laser light is coming directly through --

DR. HOWARD: That would be a failure of the protective housing.

MR. KEITH: -- and it's a failure of the protective housing, how would one -- I know probably the projectionist would notice that, but how does one monitor for that such that once the burn-through occurs, that the laser light is stopped?

DR. HOWARD: Okay, one simple way to do that -- and again, in our regs we don't want to spell out exactly how people do that. One simple way is to put a slight vacuum on that volume and then use a pressure sensor. And type T lamps have a similar -- something like that, where you just have a filament, and when there's air inside, the filament burns through, and it breaks the circuit. So it doesn't have to be complicated, but it could be.

DR. LOTZ: Thank you, Dr. Howard.

I think we're ready to move to --

DR. HOWARD: Dr. Calhoun.

DR. LOTZ: We're ready to move to Dr. Calhoun's presentations.

DR. CALHOUN: Good afternoon. I'm going to try to quickly present the topic of near infrared illuminator use for surveillance applications. We live in an increasingly surveilled state, as you all know, which has been recently supported more by the threat of terrorism. So the ability to surveil and capture images, especially at night, often referred to as night vision, is becoming very important, and it's also becoming much easier and economically feasible since the introduction of image intensifiers and thermography in the 1930s. So today, the use of infrared light to form an image is less detectable and a less invasive method for surveillance at night and can be used during the day as well. During the day, the sun provides enough infrared light to provide an image, whereas nighttime we need a near infrared light source.

Commonly, we see short-range applications where an infrared LED is sufficient to provide enough light to form an image, but at longer distances this won't work. So we then turn to near infrared lasers. When I say short range and long range, I'm generally speaking about more and less than 50 m.

These type of near infrared sources are typically solid-state, continuous-wave lasers operating between 810 and 940 nm, with powers from, on the low end, about 100 mW up to 5 W and at times even more. These lasers are typically not perfectly collimated but have some divergence in order to illuminate a larger area. That divergence can vary depending on the distance to the imaging target and also between imaging systems and even within a single system to image things that are near and far.

These surveillance systems with the lasers can be mounted both in a fixed location, for example, on a building or a tower, but also on a mobile platform such as a vehicle or a drone, as we previously discussed.

Just some examples here. There are many more than I listed. Some of the big ones are traffic monitoring, airport/seaport security, and also to accomplish tasks at those locations. So in a seaport, for example, it may be used at night to identify the numbers on the side of a ship in the distance. A lot of this technology began in the military, in defense and police space. However, now it's used more publicly. It can be used to surveil a campus, a university campus, for example.

Currently we regulate near infrared illuminators used for surveillance as SLA lasers, as Captain Hewett discussed earlier. This class of lasers or this category of lasers is output limited to Laser Class IIIa, and in this spectral range, this Laser Class IIIa is actually pulled to Class 1, which is about 0.1 mW. For reference, the correlating IEC limits are around 30 to 40 mW. They're a bit higher, and that's because this classification system takes into account the divergence of a laser, and as I said, these lasers are typically more divergent than a well-collimated laser.

As virtually all these lasers used for surveillance are larger than 0.1 mW, they would require some type of variance, and we've only allowed these applications in the defense and law enforcement space.

The reason we're concerned is because near infrared radiation at high powers can cause photothermal damage to the retina, which can lead to a permanent detrimental effect to the vision. Although at the imaging target the levels may be safe, it is possible, in the example I have on the screen, if the beam were to be repositioned and someone were to intercept the beam before the target location, they may be exposed to unsafe levels of infrared radiation.

If mounted on a drone during a close encounter, such as during takeoff and landing or during a flight malfunction or in general close proximity -- take, for example, a police drone surveilling something 100 or 200 m away. It passes nearby a building that happens to intercept the beam momentarily at a much closer range. You may be exposing someone or something to a higher level of radiation. And then we always should consider misuse by untrained persons.

For some of the longer-range cameras, the nominal ocular hazard distance can be as much as 1 km, perhaps more in unaided viewing. With aided viewing -- as we discussed, drones are commonly looked at with binoculars. This nominal ocular hazard distance can be quite a bit larger, sometimes more than 2 km. So it's a large area that we're concerned about.

It's also important to note that these illuminators are intentionally aimed towards people's faces, often for recognition purposes. And since they're in the infrared spectral range, we're not aware that we're being illuminated.

As was pointed out earlier also, administrative controls are not always reliable. Labeling and signage are not failsafe or even practical when you have a mobile platform and you have a moving zone. Training can help, but it doesn't handle unpredictable situations very well. And oftentimes the laser itself is automated and not under the direct control of an operator.

So what we're proposing is that we require an engineering control to provide a virtual protective housing, as Dr. Howard just discussed. This could include some type of sensor to prevent someone from being exposed if they were to enter a zone where the level of radiation is possibly dangerous. And this could be accomplished by turning the laser off, reducing the power, or a number of other methods. And the sensors that could be used, again, there are many options there.

With an engineering control required, we wouldn't enforce the SLA class limitation for near infrared illuminators used in surveillance systems. They would not be limited to law enforcement or defense applications. And this would also reduce the regulatory burden involved with variances for both industry and the FDA.

So the questions we have for the TEPRSSC Committee are what is your opinion regarding the potential public safety hazard associated with near infrared illuminators used in surveillance applications?

What is your opinion regarding the effectiveness of using an engineering control to create a virtual protective housing to prevent hazardous exposures?

And can you suggest another type of engineering control or an alternative solution that would better protect the public?

Thank you.

DR. LOTZ: Clarifying questions about the NIR surveillance systems?

Mr. Murphy.

MR. MURPHY: For the systems with the virtual protective housing, would manufacturers have to therefore apply to FDA in advance, similar to a laser product report, before that could reach the market? Or is it just that if they say we have a virtual protective housing, they can go ahead and sell it?

DR. CALHOUN: I think we envision it as any other required element that we already do require on a laser. It would need to be described in a product report, as are others. Those are things we would monitor, and evidence would need to be provided that it would be functional and achieve what it's intended to achieve. So I think we would look at that similar to any other engineering control, like a key switch or what have you.

MR. MURPHY: So they could not introduce it into commerce until you had looked at it and basically approved it, correct?

DR. CALHOUN: No, that's not how -- so with laser products, they can enter a product into commerce as long as they have submitted their product report and have certified it and have met the requirements of the performance standard. We do not approve laser products.

DR. LOTZ: Go ahead, Sam.

MR. KEITH: I liked that presentation. I noticed that it says that the NIR lasers are often automated and not under direct control, and back in the remotely controlled mobile laser product session, it was mentioned that it's defined as mobile laser products that require remote operational control of the emissions, and I don't see necessarily consistency here. And I imagine that in the future, with artificial intelligence, you're going to have drones that will track people because they can recognize a person moving around. Is there any thought to how to resolve these and make them more consistent? It's kind of like the battery operation of the laser pointer. I mean, you can plug it into a laptop to provide power that isn't battery operated, or plug it into a wall.

DR. CALHOUN: Um-hum. I think the goal of the engineering control is simply to preclude someone from being exposed. I think the situation, whether it's under direct control or it's more automated, may require some more thought, like you're pointing out. I think that's all I can say.

CAPT HEWETT: I think you're talking about just two different types of products that we envision there. One was mobile, one was fixed. Of course, everything that would apply here would also apply to a mobile product.

DR. IRWIN: Bill Irwin.

I just wanted to try to understand Slide 9. You talk about virtual protective housing, laser rangefinder, ultrasound, geometric calculations. So you are able to find a means by which you can actually create sufficient near infrared illumination of the object and have this protection of the individual that you're illuminating simultaneously?

DR. CALHOUN: Yes. I think that you -- in order to image, you don't need to generate levels at the image target that are dangerous.

DR. IRWIN: Okay.

DR. CALHOUN: And some of the products that have come through under variance have been able to incorporate an engineering control that monitored the space that would be hazardous and terminate the laser or provide some method to preclude somebody from being exposed.

DR. IRWIN: Okay, thank you.

DR. LOTZ: Thank you. Oh, go ahead.

DR. LINET: So if you've got a mounted sensor on a traffic pole or something, but it sweeps in a programmed motion, is it a fixed or a mobile unit?

DR. CALHOUN: That's a good question. I think we would still consider that fixed, and you would just consider the area of exposure much larger. But it would certainly require a more involved kind of control to account for all of that space, yeah.

DR. LOTZ: So obviously there's a lot here, and we will return to this during the discussion period. Now, we're prepared to have Dr. Calhoun shift topics and move into our section on Sunlamp Products - Performance Standard Amendments Update; Non-Coherent Light Sources and New Initiatives.

Dr. Calhoun, the floor is yours still.

DR. CALHOUN: Thank you. So I'm going to present this update on sunlamp products on behalf of Dr. Sharon Miller, who is attending a meeting in China. I don't claim to be an expert, but I will try to answer questions as best I can.

So I'll start with describing what a sunlamp product is. It's an electronic product with a UV lamp that emits between 200 and 400 nm. It's used for the purpose of irradiating human skin to induce tanning or a darkening effect. This would include tanning beds and tanning booths, facial units, and feet tanners.

Here are two examples of a tanning bed or booth that are most commonly seen.

The regulation of these products began in 1979 when the FDA published the sunlamp products performance standard. This was later amended in 1985 to accommodate for UVA lamps. Then in 1986, three policy letters were published to provide guidance on warning labels, maximum recommended exposure time calculations, and lamp compatibility.

Several proposed amendments to the performance standard for sunlamp products were presented at the 2003 TEPRSSC meeting. All the proposals were accepted, and I'll go through these proposals now.

The first was to strengthen the language in the warning label and make it easier to read. This included identification of risks of UV exposure, safe eyewear exposure, recommending an exposure schedule, a safe one, and also talking to a doctor or pharmacist regarding about any personal issues there may be with tanning.

The second proposal was to require a warning label to be included in the sales material targeting -- sales materials that targeted consumers, similar to other FDA-regulated products.

The third specified that modifications of a sunlamp product that results in a change to safety constitutes manufacturing. This would require a manufacturer to recertify and identify their product.

The fourth amendment was to change requirements for protective eyewear to include a cap on transmittance in the visible region and a quantitative floor on luminous transmittance, from IEC standard, and extend the requirements to all eyewear intended to be used with sunlamp products.

The fifth amendment: Replace current erythema action spectrum with universally recognized CIE reference action spectrum for erythema and change the maximum dose limit accordingly. CIE is used by FDA for sunscreen, and also by the National Weather Service, and this harmonizes with international sunlamp -- the sunlamp standard.

The sixth amendment:  Adopt the IEC's UV code approach for measuring and labeling replacement lamps.  The current approach is relative whereas the new approach would be an absolute.

The seventh:  Change approach for limiting UVC radiation exposure from the current ratio to an absolute limit, again from IEC.  The current ratio is at a ratio of emission in spectral regions, and it would be changed to an absolute limit.

And the last:  Update the guidelines for recommended exposure schedules to reduce the cumulative UV burden.  This is both per week and annually.

Then in 2014, under the Medical Device Authority, the FDA published a final order to reclassify tanning beds and sunlamp products as Class II medical devices, which would require 510(k) submissions.  They were previously classified as Class I.  In addition, all sunlamp products would bear a black box warning label, as you can see below, which reads, "Attention: This sunlamp product should not be used on persons under the age of 18 years."

More recently, in December of last year, the FDA published two proposed rules, a restriction that would prevent tanning facilities from allowing anyone less than 18 years of age to use indoor tanning devices, and it would require all users 18 and older to sign an "Acknowledgement of Risks" form prior to their first tanning session and every 6 months thereafter.  The second proposed rule was to propose the amendments to the FDA performance standard for sunlamp products, which was last updated in 1985, to adopt some elements of the IEC standard by reference.

Moving forward, we plan to publish the final rule for the age restriction and also the amendments to the performance standard for the sunlamp products.

Thank you.

DR. LOTZ:  Questions for clarification?

(No response.)

DR. LOTZ: Go ahead, Dr. Calhoun, to your next presentation.

DR. CALHOUN: Okay. Once again I'll be presenting this on behalf of Dr. Sharon Miller. We'll be talking about non-coherent light sources. I will break this down into two areas that we're most concerned with, light-emitting diodes and also UVC lamps, and then I'll pose questions at the end.

Non-coherent light sources are electronic products that emit light, commonly known as lamps. They're non-coherent, and that's the amplitude and phase of the emitted light waves fluctuate both randomly in space and time. We're going to discuss light-emitting diodes and UVC lamps, as I said.

The current effort for regulating these -- well, the only regulations we have for lamps, I should say, were developed in 1979, regarding sunlamp products and high-intensity mercury vapor lamps. Since then, FDA has not developed any new performance standards for lamps. However, as I just mentioned, the sunlamp performance standard is scheduled to be amended this year.

An LED: If you're not already familiar, it's a semiconductor diode that emits light when electrical current is applied, and the band gap determines the wavelength of light that's emitted. It shouldn't be confused with lasers. They're available in many wavelengths across the optical spectrum from 240 to 950 nm.

There is also a category often called white LEDs. This is typically achieved -- the white color is typically achieved by a combination of a blue LED that illuminates a phosphor to generate a broad white-colored light. However, you can see from the diagram that there still is a strong peak in the blue region. These white LEDs are -- they're used for many applications, which include general illumination at home and work, in tablets and e-readers, and also for outdoor lighting.

In order to discuss the safety concerns, I'll introduce first the ANSI/IEC 62471 standard for biological safety of lamps and lamp systems. They use a classification system that has four risk groups based on the potential acute hazard: Risk Group 0, which is no risk, through Risk Group 3, which is considered high risk.

The areas of safety can be categorized into a few here, but I'll discuss the blue light hazard. Blue light is hazardous to the retina due to photochemical injury that it can cause, especially due to reduced pupil area constriction when compared to white light. The peak of this hazard occurs at 440 nm, which is near the peak of the blue LED that's commonly used in these white LEDs. High luminance or hot spots can occur due to the small source size.

Glare from increased scatter can also occur, again due to the shorter wavelengths, and this can generate afterimages and temporary visual effects. They can also affect the circadian rhythm, and this can cause fatigue, suboptimal performance, and effects on long-term health.

Some of the other safety concerns which are less established but still warrant maybe a discussion are regarding chronic low dose effects. One example is age-related macular degeneration. Sunlight exposure has been shown to be a risk factor for AMD. However, no studies with appropriate animal models have been published. Most studies use rodents, and only primates and certain birds have macula. There is a study that found damage using lower-than-published damage thresholds. And there also have been published reports of retinal lesions in military personnel who have served several months in the desert that appears similar to solar retinitis.

One of the studies we're considering was performed in 2010. This was an ANSES study. Forgive me if I'm pronouncing that wrong. ANSES is a French agency for Food, Environmental, and Occupational Health and Safety. They evaluated in this study many LEDs and traditional lamps, and some of the findings are listed here. Regarding white LEDs, most types were found to be less than Risk Group 1. Some were considered Risk Group 2, which is a moderate risk similar to high-pressure metal halide lamps. Safe exposure times were between 10 and 30 seconds for white LEDs and sometimes only a few seconds for blue LEDs.

The recommendations that the study made were for manufacturers to classify and label the LEDs by risk group, and they noted that an update to the lamp standard should be provided for more guidance on evaluating LEDs. They suggested limiting LEDs for the general public to just Risk Group 1 and provide a distance at which the product becomes Risk Group 0. LED systems that were more powerful or categorized higher than Risk Group 1 should be installed only by professionals, and lighting system design should incorporate indirect lighting only to reduce glare.

The second study which I'll present is the American Medical Association report from 2016 on the effects of LED lighting. They found a strong economic incentive to overhaul existing street lighting and convert to LED lighting, for reasons discussed earlier, predominantly efficiency. However, early LED designs emitted excessive blue light, which contributes to disabling glare and visual impairment. The first generation of outdoor LED lamps, still being installed today, have a correlated color temperature (CCT) index of 4,000 K. For comparison, current outdoor lighting, typically sodium lamps, have a CCT of about 2100 K. Daylight is about 6500 K. However, newer LEDs are typically around 3,000 K, which is a warmer tone and has less of an impact on humans and wildlife.

Regarding the safety areas that I mentioned earlier, the AMA report found that outdoor LED lighting can lead to worse glare than conventional high-pressure sodium lighting. LED glare can be minimized by proper design and CCT control, which would include shielding to minimize glare.

Regarding circadian disruption, white LEDs, they found, were five times more effective at influencing circadian physiology versus high-pressure sodium lamps. Brighter residential nighttime lighting was associated with reduced sleeping times, lower sleep quality, and impaired daytime functioning and obesity. And high CCT LEDs could impact the long-term health of exposed populations.

Their recommendations were they supported the proper conversion from current high-pressure sodium lighting to LEDs to reduce energy consumption. However, they encourage the use of less than 3,000 K CCT lighting for outdoor installations. They also encourage the use of proper shielding of LEDs to reduce glare and encourage the dimming of this lighting in off-peak times.

Now I'm going to switch sort of abruptly to the other non-coherent source, UVC lamps. These lamps emit optical radiation between 100 and 280 nm. For reference, the peak emission of a low-pressure mercury based lamp is 253.7 nm. UV LEDs are also available, for example, at 214 and 247 to 280 nm.

Common uses for UVC lamps are for disinfecting air and water, for food processing and laboratory hygiene, medical device sterilization, and as consumer products for home use for sterilizing air, surfaces, and unfortunately, oftentimes no mention of skin or eye hazards occur.

The bioeffects of UVC lamps, which are often referred to as germicidal lamps due to their ability to kill bacteria and other microorganisms, they can cause skin sunburn, or erythema. They can cause sunburn to the cornea, known as photokeratitis. They can induce DNA damage, which can lead to long-term effects, for example, skin cancer. UVC lamps also produce ozone, which is irritating to the respiratory system.

The concerns we have with UVC lamps are that they're widely available as consumer products, and there's no mandatory requirements for testing or warning labels or instructions. UVC lamps have identical socket designs to other lamps, and they're sold separately. UVA lamps used for insect traps or nail-curing devices have been replaced accidentally by UVC lamps and even general illumination lamps, and there have been reports resulting injuries. Part of the increase in the availability of UVC lamps is due to the more recent development of UVC-emitting LEDs.

FDA's regulation: We don't have a current FDA performance standard or any requirements for testing or labeling of UVC lamps. The precedent is the current FDA performance standard for sunlamp products, which contains requirements regarding socket designs to avoid confusion.

Okay, so my questions: The first, does TEPRSSC have any comments or concerns about the ANSES or AMA proposals? This was regarding mostly white LEDs.

And also, does TEPRSSC have any comments about the best way to deal with potential hazards of UVC lamps, including the risk of incorrect installation?

Thank you.

DR. LOTZ: Thank you, Dr. Calhoun. And thank you also to Captain Hewett and Dr. Howard for their presentations. For Dr. Calhoun, we have the floor open to the Panel for clarifying questions.

Dr. Irwin.

DR. IRWIN: Yes, Bill Irwin.

So Slide 12, the French ANSES study, I just wanted to understand the safe exposure times that were described there, 10 to 30 seconds for white LEDs, a few seconds for blue LEDs. Is that direct exposure, to your knowledge, or scattered, you know, someone that's illuminated from above? Do you have any knowledge of what they used as an exposure situation there?

DR. CALHOUN: I'm not certain. I believe it is direct exposure, but these times are directly -- these aren't necessarily specific for this study. These are specific to the risk groups defined by the IEC lamp standard.

DR. IRWIN: Okay, I understand. Thank you.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: I have a question. Does FDA have authority over disrupting circadian rhythm? I mean, is that something that you can control?

DR. CALHOUN: Well, the FDA has authority over all light-emitting products, so they would all be subject to regulation. So in this case we have -- they are subject to regulation, I guess, whether or not they interrupt the circadian rhythm.

MR. MURPHY: But that's not my question. My question is, if a product disrupts circadian rhythm, does FDA have the authority, based on just that, to control or ban that product?

DR. CALHOUN: I'm not sure.

DR. LOTZ: Mr. Keith.

MR. KEITH: Regarding circadian rhythm, I would think that FDA would be able to identify the health effects associated with the exposure and select any or all of those that were applicable. So I would imagine that FDA can do that because if there's an adverse health effect associated with the exposure, and they're required to provide regulations for a particular product, they probably can base their regulation on any of the health effects they consider to be relevant to the situation. So I think they probably do.

We at CDC look at it that way, too. What is the health effect from the exposure to DEET, and how much exposure can cause particular health effects, and what are the health effects? And we relate it to the most sensitive health effects and the most sensitive population and apply uncertainty factors. So I think probably the same thing would apply to FDA. But following up on that, from what I've read in the studies, the circadian rhythm can be affected at exposures of as little as 4 hours. Now, I don't know whether that's cumulative, whether it's 4 hours of exposure for 24 hours or a week or a month or a year. Do you have any concept of the duration of that and whether the effect on circadian rhythm is cumulative and over what period of time?

DR. CALHOUN: I believe one of the studies that was referenced -- I'm not sure if it was in this ANSES study, but regarding this topic -- looked at people using tablets or e-readers before bed for several hours. I'm not sure of the exact specification there, but it was on the order of several hours, and they found effects regarding sleep problems from that.

MR. KEITH: Was it just like one night of exposure to the tablet, and was the circadian rhythm affected for a day, a week, a month, a year, permanently or --

DR. CALHOUN: I'm not sure.

MR. KEITH: Okay. So it could be a transient effect?

DR. CALHOUN: It's possible.

MR. KEITH: Okay.

DR. LOTZ: Thank you, Dr. Calhoun.

We are now ready for our afternoon break. We're a little bit behind schedule, but we will take a 15-minute break and reconvene the meeting at 15 minutes after 3:00. The Panel members are reminded not to discuss the meeting topic during the break among yourselves or with any member of the audience.

(Off the record at 3:02 p.m.)

(On the record at 3:19 p.m.)

DR. LOTZ: Welcome back. We will now resume this panel meeting proceeding with the Open Public Hearing portion of this afternoon session. Public attendees are given an opportunity to address the Panel to present data, information, or views relevant to the meeting agenda. Commander Anderson will now read the Open Public Hearing disclosure process statement.

CDR ANDERSON: Good afternoon. Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of the meeting. For example, the financial information may include a company's attendance of -- at the meeting. I'm sorry. For example, the financial information may include a company or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

Thank you.

DR. LOTZ: For the record, we have received three requests to speak for this afternoon's session. We ask that you speak clearly to allow the transcriptionist to provide an accurate transcription of the proceedings of the meeting. The Panel appreciates that each speaker remains cognizant of their speaking time. (Audio volume increases.)

And I'm now on much more than I was before.

(Laughter.)

DR. LOTZ: The first speaker for this afternoon, I'm going to begin with Mr. Alan Miller of Palm Beach Tan, who asked this morning to shift to this afternoon.

So Mr. Miller.

MR. MILLER: My name is Alan Miller. I have a degree in chemical engineering from Cornell University, and I'm a scientific advisor to Palm Beach Tan, which is a large operator of indoor tanning salons in the United States. The proposed performance standards, if adopted in their present form, would not -- will not comport with current scientific knowledge and will be likely or will possibly harm the public health.

Therefore -- people here before have mentioned that there's been quite some time since any scientific panel met, this Panel having met last in 2003 and the FDA's Advisory Panel having met in 2010. I don't think there's any exaggeration to say that more than half of the current scientific knowledge of UV exposure, this includes exposure from the sun, UV exposure and human health, more than half of that scientific knowledge has been discovered or published in the past 10 years. So it's a very rapidly growing field of science.

There needs to be another panel formed; it needs to have epidemiologists on it because most of the science is, as I'm sure you can understand here, is in the field of epidemiology. I'm very gratified to be able to speak in front of this Panel. I did not even know really what this Panel was until I got here. But when I heard everyone's qualifications around the table, I'm gratified to be speaking to a group of highly knowledgeable scientists, and working on this matter for the past 5 years, it's the first time I've been able to address a panel of this knowledge.

The first defect is that the proposed performance standards defeat the very purpose of the equipment, which is to provide a tan. The stated purpose is to update the exposure schedules to reduce cumulative UV exposure; that's based on experiments run by FDA to see how much, how little UV exposure you need to get certain levels of colorization of the skin. That fails to acknowledge that colorization is not what the -- is not the purpose of this equipment. The purpose is to give you a tan, and a tan involves epidermal thickening, melanization, production of melanin, and colorization. Colorization is usually quickly obtained by UVA, which oxidizes and darkens the existing melanin in the skin, but provides no protection or very little protection against subsequent sunburn.

This is very important because the principal or only environmental risk factor for melanoma is sunburn, and the United States currently has an astonishingly high level of sunburn. CDC says in the past year half of all American adults had been sunburned at least once, and 87% of all people between the ages of 12 and 18 have been sunburned at least once. The risk factor for melanoma and sunburn is an odds ratio of 2.0; it's been established by many, many epidemiological studies. So that's the first thing it does, it assumes that more UV exposure is bad for you, whereas the current science shows that the United States suffers from inadequate sun exposure; this is non-burning sun exposure.

This has been quantified within the last 2 years. The quantification is that it is -- that 12.8% of all U.S. deaths are attributable to inadequate sun exposure. That's 330,000 deaths per year as compared to 450,000 for tobacco. So inadequate sun exposure has emerged as the nation's second largest public health problem, and yet, here FDA is talking about the advantage of reducing rather than increasing cumulative sun exposure. In addition, there are three items in the performance schedule that are just adverse to skin cancer itself, adverse to the risk of skin cancer: 48 hours between exposures, two times per week, and an annual limit.

The science of UV and skin cancer formation is that for a given dose, it is less risky to get the dose as quickly as possible in time without burning, and that science has been well established by a leading scientist in the field, Dr. F.R. de Gruijl of Leiden University in the Netherlands. Because of these factors, I believe FDA is several years behind on the science. I don't -- I think that they are following, perhaps, the CDC, which is also several years behind, but that is neither here nor there for purposes of this rulemaking.

They need a new panel of highly qualified epidemiologists, and I can't remember the name of the specialty, but I think it's physics and biology together, but physical biology, which Dr. de Gruijl is, so they need to have experts in epidemiology, which is where most of the science is, and also experts in understanding what happens chemically when the sun strikes the human skin. It's common knowledge that it produces Vitamin D. It's not common knowledge that it also produces many, many other chemicals. Recently, within the last few years, it's been shown that nitric oxide, which is normally in the skin, is mobilized by ultraviolet radiation, goes into the bloodstream, and reduces blood pressure by relaxing the -- by causing vasodilation. And there are other chemicals as well. As you probably all know, it affects almost every function of the human body.

As recently as 2010, the Institute of Medicine did a study on Vitamin D and found that there were no known benefits beyond bone health, so I prepared a -- and I submitted it, a list of the most important studies since 2010, there are over a hundred of them, which is, in this field, is a very high proportion of all the work that's ever been done. So I recommend that this Committee stop this rulemaking, suspend it, and recommend to FDA that they empanel a new scientific committee to evaluate the current level of the science as it relates to tanning devices and human health.

DR. LOTZ: Thank you, Mr. Miller.

Anyone on the Panel have questions for clarification?

Mr. Murphy.

MR. MURPHY: I remember seeing photos of children in the old Soviet Union and elsewhere getting UV exposure for their health. Are there any countries that you would point to that have regulations and that have, you know, have a UV use, perhaps Scandinavian countries, that you think might be a model for the FDA? And conversely, are there any countries where we've learned bad things and should avoid that?

MR. MILLER: I'm not aware of a single country where the health authorities are up to date on the science in this field. It simply developed too quickly for the governmental health authorities in the countries to keep up with. In China they've finally gotten on to the idea that myopia is caused by lack of sun exposure, and so they're building classrooms in China today that are made completely of glass, glass ceilings, glass walls. And the reason is that myopia there has gotten up into the 90% incidence range. Myopia is not just a minor problem of kids having to get glasses. If you have myopia as a child or as an adolescent, you're much more likely to have serious conditions such as macular degeneration when you get older.

DR. LOTZ: Thank you again.

We'll move on to our next speaker. Next speaker is Dr. Frank Richarz, pardon me if I mispronounced that, on behalf of Richarz Consulting.

DR. RICHARZ: Thank you, Chair. I'm Dr. Frank Richarz. I'm here representing the two major manufacturers of sunbeds in the world; it's JK Holdings or JK North America and KBL AG, also located in Germany. Besides that they give me financial support for being here, I'm also representing the European Sunlight Association at the IEC, and I'm the Chairman of Maintenance Team 16, which is responsible for sunbeds as well as all optical radiation effects on human skin and household appliances. So even when we're talking about the correlation between IEC and FDA, I might give you some answers to some questions I've heard, for example, this morning.

What I'm showing you is a short version of an extended presentation we have already given to the FDA in March of this year which shows that the two biggest manufacturers of sunbeds supports a proposal in general, but nevertheless we have some proposals for additions, clarifications, and changes to have just the least burdensome approach and the most effective way to increase consumer protection because this is the sense of the manufacturers as well.

We fully support, maybe sometimes with some remarks, the X-Y-Code, which is intended to increase a replacement policy.  The remark here is that the IEC standard has changed the range for the Y-Code, in the newest edition, to ±25%; to change the weighting spectrum of the CIE; to change the maximum dose corresponding to the new weighting spectrum; to have an absolute UVC limit.  But again, a remark here, the absolute UVC limit, which is named in the proposed order, is not the actual IEC value, and for harmonization reasons, it would just be better to have them the same.

We think that the new wording regarding skin type I is making a much clearer warning to the customers and that the warning statements on the manufacturers' promotion material is directed to the user, absolutely okay.  The intent was to have a better warning label, and we also think that's easier to read and provides all necessary information.   And the last one, protective eyewear, there needs to be an update of the current situation in the FDA regulations, but please use again the newest version of the IEC standard because we have -- there are some requirements which also cover quite similar devices that might be in the same location covering visible or infrared radiation, and then we have just one eyewear suitable for all these appliances, and it's even marked with a name on it so that the consumer can see this is a suitable eyewear for this device.

We also see one serious problem with the new requirement, and that is that it's not covering all existing sunlamp products because that will -- only that will ensure that the intended consumer protection would be visible in the marketplace.  In our eyes, the rules need to be applied to all products, old and new; otherwise just applying it to new products, that will just delay the intended consumer protection by approximately 10 years, and fatally, the consumer will even get confused by this new regulation beside the old one and might therefore draw misinformed decisions.

And I have the major problem visible here, and this is a new proposed exposure schedule. We see here the current recommended schedule on top and the new one below. The major difference is that the old one is dividing the schedule in four different skin types, and the new one is just excluding skin type I, all other skin types getting the same dose during the tanning sessions. We have also some differences that the old schedule is divided by weeks and the new by sessions, and that we have the old one is a waiting period of 24 hours and the new one is 48 hours.

And now imagine that two of these appliances are sitting in the same salon, cabin by cabin or room by room. So someone would come in for the first session, and Room 8 is free, so there has to be a skin type done with this person, then there's a certain amount of time in Room No. 8, but if Room No. 9 is open, okay, you just have to exclude that this is skin type I, and you're sent into that room for another period of time. And if you do that with the fifth session, it's the same, a difference in the schedules, but this time it's the other way around, about the duration of the sessions. And maybe you're coming in the first time and having Room 8, the second time having Room 9, and so on and so on. I think, as a consumer, you would be completely confused what schedule to follow.

We have also shown to the FDA a solution from our side how we can -- we think that all products can be quite equal on the safety level with a simple adding of three labels for the old equipment, equipping it with a generic exposure schedule, which would -- just based on the old maximum exposure time because it will not change at all; providing the new warning label, for sure; and put on the X-Y-Code range label, and you can put that from the existing lamp label, which is on the bed already. So with already existing information, it would be easy to retrofit with three labels on beds to perform the same level of safety because protective eyewear could be the same; it would only be a skin typing for skin type I, and the risk acknowledgement is also the same.

It's not possible to do everything which is intended by the rule at the moment because, for example, there's a question for a new emergency stop on the beds, and you cannot retrofit the bed, being 5 years old, with a new emergency stop, but I think whether it's staying, this -- how it is today with the old exposure schedule or just with the new exposure schedule, but still having not an emergency stop would be the better solution to have it all looking the same. So we think that existing products will be able to reach a much higher level of safety to applying those three labels.

Short summary: Please make the performance standard mandatory for all sunlamp product in the market, and in the future, the future products with full compliance, the products in the market just getting a relabeling. For sure, it needs to be addressed in the rules. And the fourth point here, conflicting state regulations needs to be addressed as well, because in the meantime in all these years from 1986 to today, some states have just set up additional regulations on their level.

Or at least allow a volunteer retrofit of old sunbeds by this three label solution, but because at the moment, it's just not allowed to retrofit and modify the sunbed anymore without filing a 510(k). So if someone voluntarily just wants to bring the two kinds of beds and sell them on the same level, it's not allowed. There needs to be something in the rule that this might be allowed.

We have also indicated that we need harmonization with the IEC, but if we harmonize with the IEC, it would be good to use the newest edition with the correct X-Y-Code with the new exposure schedule, which is reflecting the state of the art which was decided by radiation protection authorities from Scandinavia, from France, from England, from manufacturers, from the FDA, who is in that all as well. UL is there. And we all agree that this would be the right way, but the IEC standard has a shortcoming with the annual dose, as well as it's not indicating a maximum 2 times a week tanning.

In the 878 there is a customer acknowledgement sheet, which is asked to be re-signed every 6 months, and we really ask whether if you have once signed it and if you're coming along tanning and you always see the different risk associated printed on labels and posters, why signing this acknowledgement sheet again and again?

Have new warning labels for all products. Irradiance testing is not adequately described in the rules at the moment, but there's a very good testing process in the IEC standards, so please adopt that. We don't need any 510(k) re-filing. The marking of the eyewear with a clear indication that this is an eyewear suitable to a sunbed would be very good in our eyes. And the manuals should be downloadable from the manufacturer's website.

Thank you, and I'm happy to hear questions.

DR. LOTZ: Thank you, Dr. Richarz.

Questions from the Panel.

Mr. Keith.

MR. KEITH: Sam Keith.

Regarding the acknowledgement form, that there's a risk associated with the exposure --

DR. RICHARZ: Um-hum.

MR. KEITH: -- who maintains those, and who audits those, and do organizations lose their ability to operate because they don't do that?

DR. RICHARZ: The responsible body in IEC is IEC TC 61/MT 16, which I'm heading, and we are based on the input of all the members coming into that meeting. So we have the radiation protection authorities from Sweden, from Norway, from Finland, UK, and so on, and FDA. And whoever finds new scientific evidence brings that in there, and we judge it with all our knowledge, and there's a lot of knowledge in this group, and we decide whether that needs to go into a new standard or an amendment of the standard or not. So we have done that about 4 years ago with the new exposure schedule, which is -- sorry -- very similar to what's now proposed by the FDA, and we think that's the state of the art of science at the moment.

MR. KEITH: Okay, regarding the form that the proprietor has to get the customer to sign --

DR. RICHARZ: Um-hum.

MR. KEITH: -- that they acknowledge that there is risk associated with exposure to UV radiation, and that's signed every 6 months, correct?

DR. RICHARZ: Um-hum.

MR. KEITH: Who maintains that, for how long, who -- what organizations are auditing to find out that those forms are being signed and retained, and what's the retention requirement for those forms?

DR. RICHARZ: Okay, actually that's a question you should answer to the FDA because it's there. I can answer but --

MR. KEITH: Well, I guess in other countries.

DR. RICHARZ: Oh. That's nothing which is done in other countries. This is not part of the standard, and it's not part of regulations in other countries. By the way, for sure, other countries have regulations on top of the standards as well, so -- but your performance standards is -- the IEC standard, for example, and all the regulations, how to deal with this in a daily practice, this is something which is a regulation issue, and these are in place in most European countries, in Australia, Canada, so -- but this risk acknowledgement sheet is something very special, which is now proposed for the U.S.

DR. LOTZ: We have clarification questions from Dr. Faraone and Dr. Stein.

Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I was just wondering what is your assessment of the state of the science in -- Dr. Miller mentioned that most of the knowledge has been acquired in the last 10 years, so should that be the case also, in your opinion?  Is the current proposal to exclude type I skin a measure inserted for prudence?

DR. RICHARZ:  Mr. Miller is right, there is a lot of new science, but the committee of 50 people has not decided up to now to take all this into account for changing the standard. It's for sure it's skin type I with very fair skin, and the definition is not able to tan, so the question is why should such a person tan in such a device.  And therefore, it's for the committee, it's absolutely logical to exclude them.

DR. FARAONE:   Thank you.

DR. STEIN:  Toni Stein.

Are they considered devices under NEC Code, and do they fall into having to be ground fault circuit, have ground fault circuit interrupters?  And, you know, you're putting requirements on the person who's getting treatment or whatever --

DR. RICHARZ:  Um-hum.

DR. STEIN:  -- you want to call it.  Do they also have -- exclude being able to use drinks or any liquids on the beds?  Is there -- and are they UL listed or some other listing?

DR. RICHARZ:  They are advised not to do so; it's in the instruction manual.  Some countries even post on the wall.  For example, remove cosmetics, don't use sunscreens. Sounds a bit stupid, but -- yeah, well, it's sun, and I'm used to use sunscreen when I'm going to the sun, so therefore some people do that.  So this advice is there.  But at the end, it's like going to the beach.  You cannot rule every person doing what they would like in their normal behavior, and you have to -- this is what I said at the beginning, you have to inform them that they are able to draw informed decisions.  If they still draw a wrong decision, you cannot avert that, I guess.

DR. LOTZ: Thank you, Dr. Richarz.

We will move to our third speaker from -- in the public hearing session, and the information I have is this will be a joint presentation by Sonali Gunawardhana and Jerome Dennis.

MS. GUNAWARDHANA: Okay, good afternoon. My name is Sonali Gunawardhana, and I am counsel at the law firm Wiley Rein, which is a local law firm here in Washington, D.C. I have a traditional legal service contract with the Laser Illuminated Projector Association, which is better known as LIPA. Unfortunately, they are all in China right now, so you're lucky in the fact that you get their lawyer for part of the day today. I have been working with them for the past I want to say 4 years, so I do know their issue quite well. So I'd like to thank you for this opportunity to address you regarding the need to update U.S. laser regulations to harmonize with international standards.

So I'm here representing LIPA, which is a group that was formed in 2011 at the request of the FDA to enable the laser projector industry to speak with a unified voice in regards to developing a practical and balanced regulatory approach given the limitations of the current outdated U.S. regulations and this innovative product. FDA previously issued two notices of rulemaking in which the FDA indicated a desire to harmonize with international laser standards.

However, the FDA, to date, has yet to move forward with a proposed rule, and in both circumstances, the Agency's proposed rule included a harmonization with outdated IEC standards. We have been anxiously awaiting a proposed rule that harmonizes with current international standards as it may provide a concrete regulatory approach. In the meantime, as many laser products are regulated through guidance documents, as evident by the many laser notices issued, we have focused our continued efforts to work with the FDA, primarily CDRH, to develop a workable guidance document for laser-illuminated projectors, better known as LIPs.

The FDA apparently disagrees with worldwide laser safety experts that have concluded that laser-illuminated projectors should be treated like lamp-based projectors and is now requesting that the Committee contemplate the additional requirement for engineering controls for non-cinema LIPs, which would create a distinctly separate and expensive manufacturing scheme for projectors sold in the U.S. without any concrete safety reason for doing so, given that there is no information that demonstrates that LIPs sold in other countries have posed a safety risk in need of the requested engineering controls.

So -5 is an appropriate standard for image projectors because its definition of the risk evaluation includes the single fault condition as the RG, which is Risk Group 3, projectors are for professional use, which means they are purchased by professionals and are installed and operated by professionals, not the general consumer.

So laser projectors serve as an innovated upgrade to your basic lamp projector, as you see in the back here.  Not so clear.  I think if you saw a LIP, you would be quite impressed, and you would probably opt for it instead, where in traditional lamps, an optics is replaced with a block of lasers and new optics provide the light which projects the image onto the screen.  The optical assembly of the laser lens takes the laser light, removes the laser lights coherence, turns it into broadband-like emission, and allows a broad range of wavelengths.  This is very different from the typical use of a laser where the laser's coherence of pinpoint beam and monochrome activity bring value to the final product.  The use of lasers also brings advantages in terms of power usage, color control, and brightness of images, plus these projectors are much more environmentally friendly to the earth at the end of life.

In 2013, in a seminal study by Dr. David Sliney, peer reviewed and published in *Health Physics Journal*, found that the radiance of emissions of laser-illuminated projectors are equal to emissions of lamp-illuminated projectors, which have been used for over 60 years with no record of user accidents on record. With these findings and in accordance with laser and biophysicists from around the world, the IEC and ANSI undertook the formal updating of the 60825 2006 laser standard to make all LIPs Class 1 when in operation, adopted internationally as 60825 2014 in May of 2014.

Thus, in other parts of the world when laser projectors are in use, they are classified under IEC 62471-5:2015, which is better known as the IEC lamp standard, which was created to provide standard safety for all projectors. Because the U.S. has never adopted the lamp standard, this has created an uneven regulatory framework as in every part of the world except the U.S., LIPs are treated like lamp projectors, while in the U.S. they are subject to a complicated guidance document in which some manufacturers find themselves grappling as to how to market their product in the U.S. as they do in other countries that have already adopted international standards. In the U.S., LIPs find themselves in a precarious state, given that FDA chose to issue an Immediate In Effect Guidance Document before -5 to the lamp standard was fully published and in doing so cited parts of the 2008 edition and basically increased the regulatory requirements upon LIPs well beyond any identified radiation hazards.

So we urge this Committee to make a recommendation to the FDA regarding the need to update the amendments to the laser rule to harmonize with international standards or to revise the current LIP guidance document to address the adoption of IEC 62471-5 rather than refer to an outdated IEC standard, thereby providing a vehicle for LIPs to be regulated similarly all over the world. LIPA, for the past 5 years, has worked tirelessly with the FDA to demonstrate a need for a workable guidance document given the lack of movement on the issuance of new laser regulations, even though the FDA has continually stated a need to harmonize with international laser standards. We have willingly worked with the technical and policy staff and spent valuable time and have engaged international laser, photochemical, and photobiological experts to address FDA's concerns regarding the use of LIPs on what the International Laser Committee has already deemed appropriately regulated under the international lamp standard.

As manufacturers of advanced projection systems, we can assure you we are extremely invested in the safety of our customers, the public, and the safe use of our systems, and therefore we respectfully request that you recommend to the Agency a need to harmonize with international laser standards, either through formal rulemaking or through issuance of a revised LIPs guidance document. We also urge you to adopt the findings of world-renown international laser safety experts that have determined that laser-illuminated projectors should be treated like lamp-based projectors and reject the FDA's request for additional and expensive engineering controls that would be cost prohibitive and would hamper introduction of these innovative products into the U.S. market.

LIPA is willing to work with the Agency to develop other avenues for addressing their concerns in regards to intentional steering, such as including information and a user's manual about safe use of the product and the need to supervise use of the product by adults, given that intentional steering is something the Agency feels that a juvenile population is susceptible to. Like other products that may pose a remote threat, the Agency has agreed to safety labeling as a preventative control.

So I thank you, and I'm going to turn it over to Jerry.

DR. LOTZ: Our next speaker is Jerome Dennis, who is also speaking on behalf of LIPA, I believe.

MR. DENNIS: Good afternoon, thank you. I'm sorry it's so late. My name is Jerome Dennis; everyone calls me Jerry. To introduce myself, I was hired by the FDA Bureau of

Radiological Health in the summer of 1975. I retired from FDA at the beginning of 2008. My job description at the time was international expert for laser safety standards. Much of what I will have to say has already been presented to you by other people today and has been included in the briefing package that you received.

I would like to talk a little bit about the IEC, the International Electrotechnical Commission, which develops and maintains standards for electrical and electronic products that may include engineering performance, safety, terminology, and units. And the IEC, as said earlier, is based in Geneva, Switzerland.

One of the things that was said this morning about one of the IEC committees is that it was very Eurocentric. I have been involved in standards committees for decades, and my experience has been that every committee has its own personality and its own balance, so I want to talk about IEC TC 76. We have 20-member participating voting member countries, of which 10 are very active and are listed on the screen. Our membership in TC 76 includes government safety agencies such as the U.S. CDRH; the UK Public Health Executive; the military, such as our own Department of Defense; manufacturers; users; product testing and certification laboratories.

I have to say that I was the chairman of the ICE TC 76 from 1999 through June of 2014. Now I am the vice chairman of that committee. The IEC passed a new directive saying that a chairman cannot serve a fifth consecutive term. So our members represent an excellent cross-section of stakeholders in this technology. Our members include experts in photobiology, radiometry, applications, and several of our members are extremely conservative in their approach to safety.

TC 76 is meeting this week in Beijing. If you can look very carefully, you'll see Dr. Sharon Miller, who has been referenced in these presentations; you'll see Woody Strzelecki, also from the CDRH; and you'll see Dr. David Sliney in the first row, who's also been referenced quite a bit. I'm not there; I have overriding family obligations which keep me here, so that's why you have the pleasure of my company today.

In the United States, TC 76 is supported by what's called the Technical Advisory Group, TAG. It has a similar cross-section of stakeholders to the technical committee, including CDRH. It submits comments and voting positions to the U.S. National Committee, and its members constitute the U.S. delegations to the TC meetings. I was the chairman of this TAG from about 1997 through, oh, 2013 when I decided it was time to give over the reins to a younger person. The present chairman, who supports what I'm going to say today because I've shared my presentation with him, comes from the U.S. Navy, from the same laboratory as Robert Aldrich.

The particular TC 76 standards of interest to this particular discussion are the 60825-1, which is Edition 3; it's a horizontal standard titled the Safety of Laser Products. It includes the hazard classification based on the accessible emission levels during operation; specifies controls, indicators, and warnings on the products and in their supporting literature; and the new edition allows emission hazards of low radiance laser products to be addressed by the safety standards for lamps and lamp systems in 62471 and 62471-5.

So the 62471, which the current edition is 2006, establishes the risk groups based on the accessible emission levels of lamps and lamp systems.

The new one, 62471-5, published in June of last year, contains measurement conditions for risk group determination and also -- and this is very important -- requirements for label, warning labels and instructions, and also where various risk groups of projectors can be used.

Now, the interpretation of the IEC standards with respect to LIPs is the radiation hazards are equivalent to those of projectors, conventional lamps, for the same risk group emission levels. The radiances of the LIPs are equivalent to those of projectors incorporating conventional lamps of the same risk group. To think for a moment, our old carousel slide projectors, they were Risk Group 2. There were no known injuries resulting from exposure to beams from slide and movie projectors over the many decades that they had been in homes, school, auditorium, and cinema use.

The CDRH standard and guidance policy limits demonstration laser products to Class IIIa, or 3R in the IEC world. The Immediately in Effect Guidance Document that was issued last year contains classification and requirements for laser-illuminated projectors, and that was in February of last year. LIPs that are Risk Group 0, 1, or 2 can be certified as Class I laser products. LIPs that are in Risk Group 3 are considered to be Class IIIb or IV demonstration laser products requiring CDRH approved variances in order to be imported or distributed in the United State.

Now, the effects of the CDRH policy has been excessively burdensome to manufacturers: delays in marketing while variances are being reviewed; costs in preparing these requests; and the engineering costs for meeting diverging requirements for the same model in different parts of the world; and then going along with that is market resistance. So there's confusion, in addition, in the labeling and requirements. Some Risk Group 3 projectors, if classified under the older IEC standard, would wind up to be Class 3R laser products for which FDA does not require variances for 3R but does for Risk Group 3, inclusive. And one approved variance that I have seen, and these are public documents downloadable from Regulations.com [sic], impose conditions on the manufacturer that were not only beyond the published policy, but unrealistic in they wanted the manufacturer to do things that were totally under the control of the user.

Conclusions: The IEC standards provide adequate assurance of product safety; the IEC standards represent a consensus of experts from several nations and agencies; the IEC standards therefore have the highest degree of credibility and acceptance; and there is not a scientific basis for the CDRH imposing safety requirements more stringent than those of the IEC standards; adopting the IEC standards would be the least burdensome approach to which FDA says it is committed.

So LIPA, who is supporting my preparation, my time here today, requests TEPRSSC to urge the CDRH to:

1. Immediately revise its guidance document to adopt by reference the requirements of the IEC standards 60825-1, Edition 3; 62471-5, as providing adequate assurance of protection of the public health and safety in the use of these products;
2. Adoption by reference of these two international standards into any amendments to be proposed to the CDRH radiation safety standard for laser products; and
3. If CDRH will not grant these two requests, then we request adoption of both the subclause 4.4 of 60825-1 in addition to 62471-5 in the guidance and amendments that might be proposed.

And one final thought: The OMB Circular A119 in part, Part 5 states, and I quote, "all Federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical."

Thank you for your attention.

DR. LOTZ: Thank you, Mr. Dennis. I might add, for your future reference, that OMB Circular A119, that particular section was incorporated into the Technology Transfer Act of, I believe, 1996, so it's actually in an act now, same language.

MR. DENNIS: Thank you very much. And that provides a mechanism for which government agencies can make international standards publicly available.

DR. LOTZ: So Committee questions of Mr. Dennis?

Dr. Irwin.

Yes, of each of our last two speakers, excuse me.

DR. IRWIN: Yes, thank you.

It's really great that my teacher in laser safety, Dr. David Sliney, has been mentioned by three individuals already today, and so my question is about the study that has been cited, and in particular, did this study actually describe any damage to the phosphor as part of the protective housing and whether that would lead to exposure of the Class 1 laser -- or excuse me, the Class 4 laser inside that put that phosphor there?

MR. DENNIS: Okay, your question had two parts. The first part, I don't feel that I am qualified to get into details of that study, but the second one, consider for a moment that if we have a projector in a cinema and the phosphor fails, the projector will no longer be a serviceable product. It won't perform properly; it will be taken out of service.

MS. GUNAWARDHANA: I mean, we're happy to provide you with the study that Dr. Sliney drafted and I'm sure -- I've worked with him closely. I'm sure he'd be happy to personally answer any of your questions regarding the study on the phosphor use. Basically, it's a peer-reviewed journal article. They looked at what he did; it seemed very credible, good science that backed that there wasn't any difference between a laser-illuminated projector and a lamp-based projector.

DR. IRWIN: I guess I'm trying to make sure I understand. So did that study identify any failures of the phosphor as part of the protective housing that would then allow accessible exposure to accessible emissions that might be at Class 4 or Class 3B levels?

MR. DENNIS: What I said, if I think that would happen, yeah, it would be a failure, but it would immediately result in the operator shutting it down because it wouldn't really be working; it would be -- and that's not good for the manufacturers as well. They don't want this to happen. They need reliable -- if projectors are going to be in movie theaters throughout the world, it's not in the best interest of the manufacturers not to have taken that thoroughly into account in their design and manufacturing of the products.

DR. IRWIN: Okay.

MS. GUNAWARDHANA: I'll tell you what. I will take your question back personally to Dr. Sliney and ask him if he can respond to you directly about your question.

DR. IRWIN: Yeah, part of it is trying to get a sense of how vulnerable this phosphor is to damage given that it forms a part of the protective housing, making it essentially a Class 1 laser product if it does not emit levels above 3, what I used to call IIIa, outside of that cabinet.

MS. GUNAWARDHANA: Okay. I mean, I think what we can -- because we are not the scientists, unfortunately they're all in China --

DR. IRWIN: Right.

MS. GUNAWARDHANA: -- enjoying great weather, most likely, and nice Chinese food, we are still here; we cannot directly answer your question, unfortunately. Happy to take it forward. I think what we are trying to say today is that experts, other laser experts have gotten together, have looked at LIPs, have looked at their protective housing, and have come back with the classification that all LIPs, when in operation, are considered Class 1 under IEC standards.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

From the practical standpoint, you have a movie projector, okay, and it's operating. What happens when the phosphor starts burning through, and what happens to the quality of the image? Is it degraded significantly, or is it not? I mean, what actually happens? And how does one recognize, in a mover theater, as an operator, that this bulb is operating well except that the phosphor is burning through and it needs to be replaced?

MR. DENNIS: Well, the phosphor is what actually generates the light that people see on the screen, and if the phosphor starts to fail, the image on the screen will become unacceptable.

MR. KEITH: Well, I mean, you have a certain area of phosphor and, you know, it -- as soon as it starts burning through in one particular area, is it very noticeable on the screen as it --

MR. DENNIS: The phosphor, in my understanding of the product, is that the phosphor is the image which is being projected.

MS. GUNAWARDHANA: It's collimated beams that come through, like they hit a mirror and then they project out.

MR. KEITH: I got that part.

MS. GUNAWARDHANA: Okay.

MR. KEITH: I got the technical part. I just want to know practically what do you see on the screen that would -- it would help you recognize that there was a problem? Would you recognize it before the audience would?

MS. GUNAWARDHANA: I think so. I think most of these LIPs are serviced and especially the RG3 in professional use. So they are professionals who service them, who install them, and who operate them, so I think that they are taking a good look at them to make sure everything is working correctly. It's a little bit different for the smaller, you know, projectors which are, you know, they're not as strong, and they are kind of in a different classification. The problem is that the current guidance document puts them under the old laser -- or the old lamp standard, which puts them in this kind of weird sort of situation, and they have to go to FDA for variances and for -- it's been tricky right now. I think that what we're asking for is that the Agency consider the IEC standards and the fact that you have international laser safety experts who said this is just like a lamp-based projector; it should be regulated as such. What we're asking the Agency for is to update the guidance document, the new -5 lamp standard, which will allow for trade internationally, also in the U.S. Right now there's a hindrance here because manufacturers are unsure of the regulatory scheme here, and they don't have it all over the world.

The reality is that LIPs have been manufactured and have been sold internationally without any reported issues of adverse events, safety issues. I am not a manufacturer, but I -- when I do speak with them, I've asked them if they've had any major problems; they haven't. These are built and designed to last a very long time. And so I think when they have problems, it's probably -- I'm not sure any of the manufacturers have seen any real problems yet because of the way they're designed and how long they're supposed to last.

MR. DENNIS: We also have a gentleman here from Nippon Electric Corporation who just advised that in a practical sense, the phosphor is not stationary where it could be burning through, but it's rotating. So it's a moving component.

DR. LOTZ: Okay, I think we need to try and move along. We have much more to discuss this afternoon. Thank you very much, Mr. Dennis, Ms. Gunawardhana, for the presentations.

Before we move to the discussion, is there anyone else from the public that would like to speak at this public session? I see a hand waving. Please identify yourself. And you have three minutes to present.

DR. SULEIMAN: Perfectly fine. My name is Orhan Suleiman. I'm retired less than 2 years next week from the FDA. I used to be Executive Secretary of this Committee, so I understand the issues, but the questions I have or clarifications are that this is a time of change. The Agency, it hasn't been spoken, but like everybody else, they are resource limited; they set the standard globally with standards for these products when no other such institutions or organizations existed, be they laser standards, be they all of the other products that you've discussed today or will discuss tomorrow.  And the world has caught up and in some places, you know, surpass.  So keep that in mind.  The Agency is trying to change.

I question the fact that as you put forward guidances which are not binding, they're "shoulds," how do you phase out the mandatory standards under the Electronic Product Radiation Control Act?  So I read the document as a proposed guidance, and I'm wondering why not propose rulemaking to phase out the mandatory standards and then replace them with the guidance under a different mechanism, so that would allow for the transition. When I read the guidance document, I was really confused, and I would like clarification.  It doesn't have to be addressed here, but I would like clarification as to how can you phase out mandatory standards but addressing it through a voluntary guidance procedure, so I question the process right now.

The other issue, I served on IEC committees and working groups.  It's not necessarily the most open and transparent organization.  The United States committee has one vote; when I served on these committees, we were one token government representative.  Some of the committees had more.  We had some professional representatives.  The committees were dominated by industry.  Many European nations each had one vote.  The process is not open to formal comment, open rulemaking; it's all done in closed session.  And not to detract away from the scientific and engineering expertise, but the primary mission of the IEC is to standardize; sometimes, not always, safety may not take the primary concern.  So you've got to address and weigh those factors in.

So those are my two questions.  I want to -- and I can't -- prior to this meeting, I said I want to look at some of those standards, even though I may have been involved with some of them.  I can't get them.  I have to buy them.  And it's really not very open or transparent or accessible, so those are questions I'd like to see addressed. And how the Agency moves on to the next, you know, era and maintains a balance globally in terms of safety standards for the public is another issue, but right now is the IEC or any other private organization or industry organization, should their standards be carte blanche about adopting?

DR. LOTZ: Thank you.

Mr. Murphy.

MR. MURPHY: I'm sorry. In your opinion -- sorry -- is ANSI equally guilty as IEC of not being transparent, you know, limiting votes, being industry controlled, or is ANSI perhaps better in that way?

DR. SULEIMAN: My experience -- somebody said each of the committees have their own personality, they're all respected professionals, and sometimes their interests are -- you know, I've seen how industry operates as well, and sometimes the role of the FDA is to protect the public safety and ensure that these products are safe and effective if they're medical, and these are consumer products, so they're not all medical products either.

So you have a situation where Congress passed a law that basically said no agency has any authority to protect the public against any electronic products that emit radiation, and that's when the Radiation Control Act was passed in '68, and this Committee was convened. It doesn't -- it's not premarket approval. These products are out there, and sort of retrospectively or whatever, if they see problems, they have the authority -- it's the big stick, and sometimes that enables -- I think a couple of years ago Center Director Jeff Shuren basically jawboned industry in terms of CT display for high-dose issues and said you really need to take care of your act. The Agency could have promulgated standards, but it had that authority to do so, but industry responded. I think industry, in my experience, will respond, but sometimes you need to know who you're responding to.

MR. MURPHY: Let me -- I'm sorry, let me ask again, would you trust ANSI more than you would IEC?

DR. SULEIMAN: I can't say.

MR. MURPHY: Okay.

DR. SULEIMAN: My experience with most professional -- it depends. But I'm not in a position to really say.

DR. STEIN: Point of clarification. ANSES, A-N-S-E-S, right? Not American National Standards, A-N-S-I. So I just want to make sure --

MR. MURPHY: Oh, no, I was asking about ANSI, A-N-S-I.

DR. STEIN: Because I think the standard being referenced here is ANSES, ANSES, not American National Standard.

DR. SULEIMAN: But it doesn't really make a difference. My point is my experience with most of these professional groups -- I thought it was ANSI as well, American National Standards Institute. They do good work, and they really bring the professionals at the cutting edge to the table, and it's great that the FDA can interact with them, not always as easily as you may think. I mean, a lot of times funding would limit even their participation, but --

COURT REPORTER: It does matter to the transcript.

DR. SULEIMAN: Okay.

COURT REPORTER: A-N-S-I, American National --

DR. SULEIMAN: Standards Institute.

MR. MURPHY: And if I could just point out a difference between ANSI, the SAE G-10, which has worked on safety for lasers in aerospace that I've worked on for a couple decades, IEC, they would give a lot more time to some of these issues. Right now, the FDA has asked 22 questions. We have heard -- it's been like 4, 3 hours. We now have 11 people to answer your 22 questions in less than a half an hour, and by my calculation, that's about

8 seconds per person per question. So I think in terms of criticizing committees for not getting into the details, you know, this Committee, unfortunately, can't get into some of the details that they should.

DR. LOTZ: And with that, I'd like to declare the public session of this -- public open session of this part closed, and we'll turn to discussion section, so Patrick, would you like to have the first 8 seconds?

(Laughter.)

MR. MURPHY: I'll turn that over to -- I do have --

DR. LOTZ: No. Excuse me for that. I just -- your summary was well spoken. I've been nervously watching the clock over here myself.

So we have our FDA speakers at hand, and I see a hand up, so we'll move right to it.

Dr. Irwin.

DR. IRWIN: Yes, thank you.

First, a lot of my questions answered earlier, and I apologize for asking some questions that were beyond clarifying earlier that took us a little bit of extra time, so I'm going to try to make a couple of brief comments and question. First, I want to thank everyone that participated here, including the FDA, on the information shared with us today. It's very valuable, and the care is obvious from all perspectives. I did want to try to get some answers to -- an answer maybe from FDA on the two questions I've posed and not got answered yet. And the first is what fraction of sunlamps are used for tanning versus medical care? And the second is, is there data about the failure of phosphors in laser-illuminating projectors?

DR. CALHOUN: William Calhoun.

I presented the sunlamp information. I really don't know what fraction are used for medical devices, but I can refer that question to Dr. Sharon Miller, who may be able to answer that.

DR. IRWIN: Yeah, the reason that I asked that is, to be quite frank with you, I think that medical applications are very important and are really to be considered somewhat separately than some of the what are often cosmetic purposes of lamps for tanning, etc., despite some of the testimony given here today. So I appreciate if I could get some answers to that; that would be good.

And then the second question, anyone -- I know you spoke to the data from Dr. Sliney about the LIP, or the LIPs previously. Do you have any idea how often the phosphor may fail as part of the protective housing on these lamps?

DR. HOWARD: Yeah, Lowell Howard.

As for phosphor failure, these are new products, and I don't have data on that. I don't have access to data on that. The manufacturers would have that data, and perhaps we can work with them to get that. As for other types of protective housing failures, for some of the earlier projectors, I'm aware you can just look on YouTube and see where certain types of projectors 4 or 5 years ago were opened up to harvest the laser diodes, and in some cases the -- this involved overrides of probably some of the systems, normal interlock systems, but it was quite -- you know, people were harvesting blue laser diodes out of projectors because it was cheaper to get them that way, and I believe Captain Hewett did some work to make that a little bit harder.

DR. IRWIN: That would be good data to have to reinforce your position that you want to take action relative to these lamps in projectors, to have some sense that it is a real problem that someone walking in front of that projector, if it was laser lamp instead of the lamp that it has, would be at risk.

DR. HOWARD: And to clarify that, that would be -- that's just to -- even if the phosphor is perfectly performing, for Risk Group 3 LIPs, if you're close enough, it's a nominal hazard.

DR. IRWIN:  Right, right.

DR. HOWARD:  Has nothing to do with the phosphor issue.

DR. IRWIN:  And are those only Risk Group 3 fixed, or can they be mobile?

DR. HOWARD:  Well, what we're working to move toward is what we publicly disclosed today, is we would like to see -- we would like to make it possible for Risk Group 3 projectors to be in fixed applications other than theaters and to do so with an effective engineering control that doesn't allow -- that doesn't need a variance process that's complex and burdensome.  And this is going to require -- this is going to take some time; it will probably require some changes in the rules for that to happen.  We're just publicly disclosing that we are considering this and contemplating engineering controls for that.  I see it as an expansive thing that allows them to do some things that are hard to do right now.

DR. LOTZ:  I think I'm going to suggest that while we're on that topic, as a result of Dr. Irwin's question, we try and deal with the aspects of the questions to TEPRSSC on the lamps for general illumination and LIPs.  Dr. Howard, I don't know if you want to bring those questions up on the screen from your presentation, but I'm going to suggest to the Panel that we look at that specifically rather than hop around to all the rest and then try and move through them at the risk of a very limited amount of time yet this afternoon, but I'm -- I will put you on warning right now that I think we'll go a little past 5 o'clock.

Mr. Keith.

MR. KEITH:  One of the public presenters mentioned that the phosphor rotates, so I'm online here trying to see how the lasers are related to the phosphor, and from one of the diagrams, it appears that the phosphor is external to the laser and that the phosphor -- the laser beam exits the laser and then hits the phosphor that's rotating, and it goes through a diffuser and then a phosphor. So I don't understand the architecture of these devices, whether the phosphor is an internal component of the laser itself, or is it peripheral accessory that's required for the operation, in which case the laser would probably be looked at separately as opposed to the phosphor.

DR. HOWARD: These are internal beam pass part of the product. They're complicated products because some won't even use a phosphor, and some are hybrid and use lasers and LEDs. Industry will use whatever mix of light sources happens to make sense economically at the time to get the job done and to get --

MR. KEITH: Well, then that's --

DR. HOWARD: -- the right color balance.

MR. KEITH: That's like the four-color laser combination where you don't need a phosphor.

DR. HOWARD: Correct, the tetrachromic, yeah.

MR. KEITH: So if you start with a blue laser, you need a phosphor in order to have a light frequency change.

DR. HOWARD: Correct.

MR. KEITH: Okay. But if you're using a four-laser combination, the four would go together to form the white light that you need.

DR. HOWARD: Correct.

MR. KEITH: Okay.

DR. HOWARD: Right. They're not simple products.

MR. KEITH: Right. And the phosphor is always internal to the tube. Always. It's never external to the tube.

DR. HOWARD: The phosphor is always inside the projector.

MR. KEITH: It's inside the projector, but is it internal to the laser itself, or is it external to the laser? Is the laser and the phosphor encapsulated in the same bulb housing?

DR. HOWARD: The laser and the phosphor, there is a protective housing around, you know, the laser product. The laser itself is often -- an array of diode lasers, but that's not -- you know, the protective housing is bigger than that. The protective housing is what keeps light from exiting the laser product itself. Does that clarify?

MR. KEITH: Right. And so that's why you want interior control so that when you remove the screws, you don't have people exposed to --

DR. HOWARD: And that's -- I mean, the main -- that's a lamp thing as well. It's not necessarily -- and there's a variety of engineering controls that can be used to accomplish this end. We're not trying to say how to do it. It's just that's -- we trust cars to apply their brakes and stop themselves with engineering controls now, and we think that a projector should detect that there's a breach in the protective housing if it's unattended, and a projector should be able to dim itself when someone's face is stuck in front of it.

DR. LOTZ: In looking at the questions Dr. Howard has brought to us, I'd say it's clear that one of the concerns is about this whole aspect of how the lamp housing and how the light is produced. But I want to direct our attention to the other questions: What's the best way to assure the safety of these products? Do we think that it needs a performance standard or a combination of performance standard and lamp standard?

There are some other questions here that -- Dr. Lambeth.

DR. LAMBETH: Yeah, I was a little confused by the geometries of the systems myself. My understanding is the laser -- the phosphor, which is a converter, a down converter, is not freestanding, right? It's on a substrate of some form; is that correct?

DR. HOWARD: Yeah, it's always on a substrate.

DR. LAMBETH: Yeah. So there's two different approaches here that we're talking about. One case is the phosphor is there converting the deep UV into various colors or white, and the other one is that the laser beam themselves are the color source, and there is no phosphor, right? So it seems to me there's two separate problems, and if you have a situation where the lasers are coming out directly, you have to sense for that laser light if you want a protective housing, virtual housing for that. But in the phosphor case, there are some other engineering solutions that don't require active engineering; you just build it at the beginning. It's not something else that could fail.

I mean, a very simple statement that I could put an absorbing glass as the substrate for the phosphor, okay, that only absorbs in the deep UV would eliminate the deep UV from coming out even if phosphor had a hole in it, right? In fact, I could -- without probably too much difficulty, I could probably make that a dielectric mirror that reflects the UV back into the phosphor and improve my efficiency a little bit. So it seems to me that could be drawn out separately from the situation where the lasers are coming out directly and now you're totally exposed to the lasers themselves. But those are not deep UV lasers; those are visible lasers.

DR. HOWARD: Right. And EPRC regulations have had -- I mean, I would -- hearing that description, I would describe that as a failsafe system, and there's a long history of that, and so, you know, you could word it -- it all depends on how you word something. It would be failsafe or -- you know, failsafe or an effective engineering control in terms of regulatory language. But that's something that, you know, needs to be considered very carefully.

DR. LAMBETH: If I'm a manufacturer of these, I'd do one versus the other, and I can see how a regulation that's addressing one makes my product more difficult to make, even though I'm not actually building that kind of product, so, you know, how you separate them is, you know, really a convenience issue in issuing a regulation.

DR. HOWARD: So I've got one more, there's one more question. If that's the end of that one. And this -- right. Do you want --

UNIDENTIFIED SPEAKER: Can we change topics just a bit?

DR. LOTZ: Well, let's answer his question here. He just put up a different one.

DR. HOWARD: Do you want to go back to that one?

DR. LOTZ: Or at least take stock of whether anyone wants to comment on that.

Mr. Murphy.

MR. MURPHY: First of all, my understanding of how these projectors work, including the ones where you got the lasers and there is no phosphor, is that essentially there's a subsystem inside that is creating a bulb that's going to do a big blob of white light that will get modulated or possibly the laser is modulating it directly, but in no sense do you have individual beams coming out, unless there is some kind of massive failure, which I assume is something that's addressed in the standard. So then, to me, if I'm understanding, the big question is you have this projector, and it's putting out a lot of light, and if you put your eye in the light, is your eye going to suffer some damage? Would that be correct that that's the primary concern?

DR. HOWARD: Yeah, thermal injury, potential for --

MR. MURPHY: Okay.

DR. HOWARD: -- thermal injury with those --

MR. MURPHY: And then so my question now for the people from LIPA is they seem to be saying that in the entire history of slide projectors and other projectors, that there's been this one incident in the Soviet Union. So what am I missing? Why is it now a different thing to worry about these projectors, because there's a laser as the lamp source? Assuming that outside of it, it's essentially the same as a high-powered, you know, conventional bulb.

DR. HOWARD: Okay, let me back up a little bit because there's two issues here, and I think they're being a little -- they might be easily confused.

MR. MURPHY: Sure.

DR. HOWARD: One is, you know, the protective housing issue that you're talking about, and that's true for lamps and LIPs -- you know, a lamp is a part of a LIP -- but you know, lamps, automotive headlamps, things that are obviously easily broken, the lamp up there, and that's a protective --

MR. MURPHY: And that's the question --

DR. HOWARD: Yeah.

MR. MURPHY: -- that you're asking, which is about the virtual protective housing? In other words, you're assuming that --

DR. HOWARD: Okay, hang on. Yeah. So that's one protective housing issue. With LIPs specifically -- and this is specific to LIPs and I probably poorly worded things -- with Risk Group 3 and, you know, you are correct and Dr. Sliney is correct; I don't disagree with him there on the number of injuries. They've had effective engineering controls in theaters for, you know, protecting the public from a Risk Group 3 projector. As you move forward and get these projectors out of theaters and people want to use them in large hotel ballrooms and laser light shows and things, put them outside to project on the walls on buildings, you can either do that with a variance or you can just make the product safe with an engineering control that will dim it and provide that virtual protective housing and that's --

MR. MURPHY: And I understand that.

DR. HOWARD: Okay.

MR. MURPHY: And that sounds cool and stuff. I'm sure it costs a lot, and it's technically complex. But assuming that these projectors are putting out the same amount of light as, you know, old carousels and so forth and that the light is diffused and we're just worried about the ocular hazard, if there hasn't been injuries from conventional sources of this type, why are there now new engineering controls needed?

DR. HOWARD: We're looking at engineering controls on Risk Group 3 projectors.

MR. MURPHY: Are you saying that everything that Dr. Sliney studied was not Risk Group 3, or the Risk Group 3 at that time was only in cinemas and now they're smaller and more portable?

DR. HOWARD: No, Risk Group 3 were only in cinemas in Dr. Sliney's --

MR. MURPHY: With a conventional light source?

DR. HOWARD: Yeah.

MR. MURPHY: Yeah, okay.

DR. HOWARD: His survey covers all projectors.

MR. MURPHY: And so now the idea is that Risk Group 3's are getting smaller, and you can put them in your briefcase or whatever and have a Risk Group 3 --

DR. HOWARD: Just trying to look a little, be a little future forward and --

MR. MURPHY: Okay, okay.

DR. HOWARD: -- and see that, you know, these are going to be popularly applied, and we have a little bit of a vision into that because --

MR. MURPHY: Okay.

DR. HOWARD: -- we have a variance process and we see things. So in some -- you know, it makes a lot of sense to --

MR. MURPHY: So it really is a new animal in that it's now portable, it's out of the cinema, the Risk Group 3 projectors. And you wouldn't want --

DR. HOWARD: It would be --

MR. MURPHY: You wouldn't want a child running in front of that one, for example, if that --

DR. HOWARD: It would be --

MR. MURPHY: -- was a Risk Group 3?

DR. HOWARD: -- a new animal, yes.

MR. MURPHY: Okay, okay.

DR. HOWARD: In a variance -- you know, variances are somewhat effective, I mean, but it's another form of administrative control. You get the variance, and you agree to use it in a certain way, you know; that's how use instructions get into this because it's a manufactured product, you know, a laser light show, and this would be a little -- a different approach to that where we're engineering controls to just make for a safer product and a less burdensome regulatory approach.

MR. MURPHY: Okay, okay. Thank you for clarifying that.

DR. LOTZ: Dr. Stein.

DR. STEIN: Toni Stein.

You have the specific protective housing. Would you be -- would a sensor do, instead of a protective housing, if you had an adequate sensor to turn it off?

DR. HOWARD: Well, that's the idea. I mean, we -- you know, again, going back to self-driving cars, you know, you've --

DR. STEIN: Right.

DR. HOWARD: -- got a sensor that looks forward --

DR. STEIN: Yeah.

DR. HOWARD: -- it applies the brakes. And you would need some obviously light, you know, light emission occurs over the inside of a sphere, you'd need some protective housing, but we're talking about the portion, strictly the portion in front of a projector that, you know, if your face is there --

DR. STEIN: Um-hum.

DR. HOWARD: -- 20 centimeters away, and you risk some type of eye injury or your child risks some type of eye injury; if it's an unrestricted product that's sitting on a coffee table, as products will, something should sense that. Sensors are getting quite cheap now for that.

DR. STEIN: Yeah. I just heard it's a very expensive proposition from public speakers, and I just wonder if all of them are expensive because sensors can be very low cost.

DR. HOWARD: I believe you are correct there --

DR. STEIN: Yeah.

DR. HOWARD: -- and I'm going to leave that to the market --

DR. STEIN: Okay.

DR. HOWARD: -- to deal with. We're putting it out there that we're contemplating this.

DR. STEIN: Yeah.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

Did I understand that conventional lamps are like Class 2 or 3 but that these LIPs can actually extend into the Class 4 laser category that are unlimited in power, and if so, would you make a special category to -- as a 3C to limit their power? Is that one aspect of it? Or if you go to Class 4, you have no control on what the manufacturers provide as far as a power source, which makes these things potentially damaging at long distances.

DR. HOWARD: You could build -- if it is equivalent to Class 4, then, yeah, the sky's the limit. It's a practical matter, though.

Go ahead, go ahead.

MR. KEITH: It says one important aspect of this guidance document is that RG3 projectors are considered to be equivalent to Laser Class 3B and 4 projectors. And Class 4 is an unlimited class.

DR. HOWARD: Right. In theater use, they're --

MR. KEITH: Like the super dragsters.

DR. HOWARD: Well, but there's long -- the theater industry has standards for how bright a screen should be to be comfortable, these -- yeah. The theater film projectors have been around for a long time, so they -- there is such a thing as a projection screen that is too bright, and it just doesn't -- you know, becomes prohibitively expensive and not practical to make a projector that's seriously bright, although I wouldn't, you know -- once you allow -- you know, once something is there, sure, I suppose somebody could build the behemoth projector that would project a movie on the side of a dam.

MR. KEITH: It's kind of like the laser light show at Stone Mountain outside of Atlanta, Georgia, where they're projecting, you know, about a half a mile onto the face, on a stone face.

DR. HOWARD: Right. Yeah, there's, you know, there's a universe of possibilities, and if something is available in a standard, somebody will eventually build something that's right up to the MPE limit that's in the standard, virtually assured.

MR. KEITH: If I could just respond to that, since our members do things like that, there you have a beam of light that you're moving around very fast to create those images, so if you take the light from that same laser and you spread it out like a laser-illuminated projector, to be basically like this kind of projector, a raster scan image, it's going to be super faint. So although as you said, you know, the sky is theoretically the limit, practically, you're not going to use a LIP projector for Stone Mountain. Or if you do -- you couldn't do it today.

DR. LOTZ: Thank you, Dr. Howard.

I think I'd like to shift to one of our other topics, and I'm going to call on Mr. Aldrich because he had some items earlier that I cut him off on. So Robert, it's yours.

MR. ALDRICH: Thank you very much. Robert Aldrich.

These are questions having to do with the revised rules for the lasers. The question of incorporating versus including, I know I've talked previously with FDA about concepts having to do with what is a laser product, and I'm concerned -- I read through all the read-ahead material, and I'm concerned that perhaps I'm misunderstanding. For example, an aircraft that has a laser capability within it, whether that would be considered -- what defines the laser product and what is not a laser product. I think the intention with the revised rules is to clarify that, but I'm not sure that I understand how that's been clarified, so I would ask for clarification on that.

CAPT HEWETT: Okay, so you have laser products that are both components and then finished laser product. Sorry, can't hear me? Say laser products that are composed of -- a finished laser product, for instance, and that's in the regulation under component. So you have laser products that are components, and under this new concept, you have something that's called a finished laser product that's neither a part nor a component. So we're trying to make a distinction that laser products are components and/or finished products.

MR. ALDRICH: Perhaps I could give an example that would help make this go faster. I know that say, for example -- I work for the United States Navy -- an aircraft that has the capability of performing functions using a laser. It's typically done with an add-on piece that is attached to an aircraft, and for that purpose, I believe we would say that the aircraft itself is not a laser product; that is correct, is it not?

CAPT HEWETT: That's correct.

MR. ALDRICH: Okay. Currently, there are aircraft in production that are including permanent installed laser capabilities within the fuselage of the aircraft itself. Would that be, that aircraft be a laser product? It's not an add-on piece; it is integral to the function of the aircraft. Would that make the aircraft the laser product?

CAPT HEWETT: If the laser product was an airplane, and it relied upon the laser system, the laser emission, to fulfill its purpose, which would be fly, then yes.

MR. ALDRICH: Well, the purpose of the aircraft would be to fly and perform a mission. So would that -- is this a gray area or is it --

CAPT HEWETT: It's a gray area. I mean, a laser manufacturer -- I mean, a manufacturer of an airplane could produce their own laser product and install it in their aircraft.

MR. ALDRICH: Okay, my --

CAPT HEWETT: They could certify that particular laser product separately from the aircraft.

MR. ALDRICH: Because I did read that there was talking in here about them being a distributor versus a manufacturer.

CAPT HEWETT: Yes.

MR. ALDRICH: And my concern has to do specifically with the military exemption that we currently possess for certain types of lasers, and my understanding is that the military exemption is a product that the DoD can allow manufacturers who deliver products, laser products, to the DoD to utilize, and if the laser component is not -- or perhaps I'm using the wrong word. The laser device is not the aircraft, and they are not providing the laser device to the DoD directly, whether or not the exemption in its current form would be the avenue for which the DoD should move forward or whether that would require a modification to how business has been done.

CAPT HEWETT: Well, I'm not fully understanding what you're talking about; I'd hate to make a judgment on that. I think that's something we've got to talk about in more detail because this re-proposed rule has so many elements in it regarding, you know, perhaps a product that's installed, a finished laser product, a component. I think I'd probably spend the remainder of our time just talking about these subtleties, so I'm not real sure how to address this right here at this point.

MR. ALDRICH: I know we're limited for time, so I'll set that one aside. I've got a couple other issues. The revised rules here are using the term "light," referring to laser light, and as I understand it, that's a photometric unit, so it's confusing me. If, when we refer to laser light, are we only talking about visible wavelengths, or is that just a more common use of laser radiation?

CAPT HEWETT: The latter.

MR. ALDRICH: Okay. I'm concerned that -- let's see here. The wavelength requirement of 410 to 610 nm, I spoke a little bit to that briefly; we were short on time. I know that came off -- it didn't get completed. I am extremely concerned about limiting laser pointer capability to wavelengths outside that region. There are applications that require laser-pointing capabilities within a non-darkened ambient environment.

I believe that limiting laser pointers to exclude 410 to 610 nm would preclude the use of an established need for laser pointers, and that is to -- the purpose of a laser pointer is to point at something and being able to see what you're pointing at, and unless you're in a darkened environment, if you're outdoors and you try to use something like this soon-to-be-made-illegal green laser pointer to point at something outside, you would not be able to see it if were a red laser pointer, so I'm concerned that, although I appreciate the need that such a rule might possess -- I do acknowledge that there are an unacceptable number of aircraft illuminations using green laser pointers -- I disagree that most of them necessarily happen at night. I just think that because it's more noticeable at night, that that's when they are reported, but I believe that this rule change would significantly negatively impact valid reasons for using laser pointers to avoid the possibility of misuse.

So I did want to see if there was any other considerations that were -- or any other ideas that were being considered other than banning green laser pointers; there's many of them out there. I'd also like to know what happens. Are they grandfathered for people that already have green laser pointers, or what would happen with all that?

CAPT HEWETT: Well yeah, we couldn't be able -- we wouldn't be able to pull back laser pointers that are green; the FDA wouldn't be able to do that. That's why I said earlier that once we determine that they are defective and a public health hazard, we would perhaps rely more on federal -- I mean, on state and local laws and ordinances that would recognize the use of the green and the blue to pull those out of the market.

MR. ALDRICH: Personally, I would argue that a green laser pointer, using green in order to reduce the amount of energy you need to have an effective spot seems like a specific use and certainly not a defect; that's my personal opinion.

CAPT HEWETT: I can see that as well.

MR. ALDRICH: So that was all I had with that.

CAPT HEWETT: I just want to address that --

MR. ALDRICH: Please.

CAPT HEWETT: -- because I think we could say specifically surveying, leveling, and alignment products that are used in daylight situations could be green, you know. Let's say you have a transit that uses a green laser during the day; I mean, that's a legitimate use, you know, of a green laser. It's not a pointer. It's not readily available from the dime store, you could just pick it up and shine it at an aircraft. It would be an engineered product for that purpose for surveying, leveling, or alignment purposes, and I think that would be a reasonable accommodation for the green.

MR. ALDRICH: Okay. If I understand correctly, are you suggesting that LiDAR be limited to Class 3R and less?

CAPT HEWETT: That's correct. And we would certainly work with the industry to put variances in place.

MR. ALDRICH: That would fall kind of in a category like current laser light shows, though, because really I don't know of a LiDAR system that could perform its mission and be Class 3R or less. Almost any LiDAR I've ever seen is Class 3B or 4, typically 4.

CAPT HEWETT: Yeah, there would be -- then we could probably take the approach of, like I said earlier in the presentation, that there is the concept we've had all along for several years about virtual protective housings and how they've been interlocked in the past under the conditions of a variance where you had, let's say, platform-specific weight on wheels interlock, altitude interlock, some other suitable airlock for the use that would preclude the need to get a variance, so we could build that into the regulation so that those interlocks were engineered into the product from the start.

MR. ALDRICH: So really highlighting the emphasis of accessible emission?

CAPT HEWETT: Yes.

MR. ALDRICH: Okay, okay. That makes sense. And the last thing that I had here, I believe -- oh, no, I had two things, I'm sorry. You had said in the presentation that the FDA rejects the IEC's allowance to not require a remote interlock connector for handheld; was it handheld type --

CAPT HEWETT: Battery-operated Class 3B lasers.

MR. ALDRICH: Yes.

CAPT HEWETT: Basically pointers.

MR. ALDRICH: What purpose does a remote interlock connector have if it's battery operated and handheld? I mean, isn't it -- the remote interlock connector intended to be something for an institution which would take away --

CAPT HEWETT: You know, the point --

MR. ALDRICH: -- the whole purpose of having it battery operated and handheld?

CAPT HEWETT: The point that we were trying to make by rejecting that is that let's say you did have a product that we were writing a variance for that was a handheld battery-powered laser, and we were writing a variance for it to exceed the Class IIIa limit; let's say it was 500 mW.

MR. ALDRICH: Um-hum.

CAPT HEWETT: We wouldn't want to necessarily remove the remote interlock connector in that case because we don't know what that particular product is being used for.

MR. ALDRICH: Okay, okay. Okay, so you just want to tie your own hands with that?

CAPT HEWETT: That's right.

MR. ALDRICH: Okay, that makes sense. And the final one, I promise this time, the remote control, the laser on a drone.

CAPT HEWETT: Yeah.

MR. ALDRICH: Okay, that issue. I believe that you had put in here that you would require an emission indicator and beam stops?

CAPT HEWETT: Right.

MR. ALDRICH: And it said for all; it didn't say regardless of laser hazard class. Would you -- did you mean for it to be for all, I mean, for a Class 2 or a Class 1 or even a Class 3R laser that would be on one of these things? Would it be necessary to have those capabilities on something as simple as that?

CAPT HEWETT: I don't believe so. We'd want to go for the higher-risk products.

MR. ALDRICH: Okay, okay. So I just -- it was a --

CAPT HEWETT: Class 3B and Class 4.

MR. ALDRICH: Thank you very much. Thank you.

DR. LOTZ: Dr. Stein, I believe, is next.

DR. STEIN: Toni Stein.

Just on the SLA idea that you were just brainstorming about, just that it -- be sure to keep in mind that during driving on streets, that temporal light artifacts from the use of any kind of light source can cause like not a blinding but distortion in seeing in the dark for other things because you're stuck with the old view, and as well to try and harmonize with IEEE 1789 on their flicker standard that's in place from 2015, because that wasn't mentioned.

CAPT HEWETT: All right, noted. Thank you.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: Well, again, you've asked 22 questions, and I have 22 answers, and I have no time, so I'll try to keep to the important ones. I do want to say, first of all, I have great admiration for your efforts and creativity in these areas. I mean, definitely something needs to be done about -- I'm going to speak about laser pointers. Definitely something needs to be done, and I have great sympathy for the budgetary and legal constraints under which you guys work, so I know it's not easy. I made a little chart here of the laser colors that you're proposing and the glare distance, the distance at which it would cause glare according to the FAA standards.

DR. STEIN: Thanks.

MR. MURPHY: I made a few copies. So this line right here is the line under which glare would not -- is the line under which you want laser pointers to be legal. So anything above this produces too much glare for the pilots. And this is using 5 mW and the wavelengths that you were talking about. If you just say we're going to make all the laser pointers 1 mW, well, they now fall below that line; in other words, they're not going to cause as much glare, and you've now harmonized, so to speak, with the rest of the world where 1 mW tends to be the standard for laser pointers rather than 5 mW. So my colorful demonstration is a simple question: Why not just go to 1 mW limit for laser pointers, sort of finalize?

CAPT HEWETT: Well, I'm not sure how to answer that without further research. But I would like to say that my understanding is that even 1 mW, it depends on the distance and the tightness of the beam, it could still cause glare, distraction, afterimage. It's --

MR. MURPHY: Well, yes, but --

CAPT HEWETT: Especially at night.

MR. MURPHY: But again, the ones that you are proposing here, for example, you have a limit of 610; that causes glare for a 5 mW laser at over 750 feet, whereas if you just say, okay, we're going to make it any color you want but now it's 1 mW, just like all the other countries, you're at about 400 feet maximum. So if it's the glare that you're looking at, the visual disruption --

CAPT HEWETT: I think once we get into the milliwatts, then we start to look at what would we be able to practically do with a 1 mW limit versus immediately recognizing that someone has a blue laser in their hand or a green laser in their hand and be able to say that that particular product, due to its color alone, is a hazard versus stopping someone and saying I've got to take your green laser and I've got to measure it to determine if it's a 1 mW laser or not. And other countries, I think, are not able to do that level of enforcement so -- I mean while it sounds like a good idea, I think we have to fold in the practicality.

MR. MURPHY: So you're talking about enforcement at the sales level because there are millions and millions of green laser pointers out there --

CAPT HEWETT: Right.

MR. MURPHY: -- and so you can't go up to somebody on the street, currently under federal law, and say I take your green laser pointer. You were talking about maybe the states could have something that --

CAPT HEWETT: Right.

MR. MURPHY: -- which may or may not be reasonable, you know; that's fine.

CAPT HEWETT: Yeah, it --

MR. MURPHY: So your approach is from a wavelength standpoint, just to make it easier for enforcement, those sales.

CAPT HEWETT: I think that's a practicality that has to be considered, you know, if you're --

MR. MURPHY: Okay.

CAPT HEWETT: If you're going to try to do --

MR. MURPHY: Well --

CAPT HEWETT: -- something like this, you have to be practical.

MR. MURPHY: As I said, I admire your creativity.

CAPT HEWETT: Thank you.

DR. LOTZ: Let's go this way.

Dr. Lambeth.

DR. LAMBETH: It's not that I want to argue with you, but I agree with my colleague over here about eliminating the green laser effectively, okay, which puts out less power means that people move into the red, which is readily available, with high power for pointers, and you've excluded those from your regulation.

CAPT HEWETT: It would still be class limit, Class IIIa for red laser pointers.

DR. LAMBETH: You know --

CAPT HEWETT: That's what it's been since the '80s.

DR. LAMBETH: The first laser pointer I saw was a colleague of mine who walked up on the stage carrying a gas laser and started pointing it at things, including the audience, okay, and people will find a way to do these things, and when you remove something that's relatively safe from their access, they will go to something unsafe. I just -- I understand your ideas and concepts, but the reality of it, to me, is that people who are out there shining light into the cockpits of planes that are going over, which is how this sort of got started, I think, okay, they're going to find a way to do that terrible thing even if you removed all the laser pointers, you know, from all the people that are using them properly, you know, because lasers are ubiquitous now.

CAPT HEWETT: Yes, they are.

DR. LAMBETH: The power is ubiquitous, and we know that's illegal.

CAPT HEWETT: That's right.

DR. LAMBETH: Okay, so they should be arrested and put away, okay, and a few demonstrations of that big time might do it. It's really not an FDA thing, I think. And I -- you know, having used laser pointers for years, I can tell you just, you say you give me that red laser that's 1 mW and nobody can see it. You know, you're --

CAPT HEWETT: I think that --

DR. LAMBETH: -- trying to shine it onto a screen that's already illuminated with a slide, and it just doesn't work.

MR. ALDRICH: Yes, if I understand -- I'm reading through here. I thought I'd seen this, but I wasn't sure until you said something here. You would remove laser pointer from products described as surveying, leveling, and alignment, correct?

CAPT HEWETT: Correct.

MR. ALDRICH: Okay. And that is why they're limited to 5 mW.

CAPT HEWETT: Right.

MR. ALDRICH: So if you remove them from being that, they're no longer limited by law to 5 mW.

CAPT HEWETT: Right, you would correct that.

MR. ALDRICH: So --

CAPT HEWETT: In the regulation, in the proposed rule, you would --

MR. ALDRICH: You would correct it to make them 5 mW again?

CAPT HEWETT: That's right.

MR. ALDRICH: Oh, okay. Because -- yeah. When I read that, I was like the same thing. It's like so you're saying that they could do red, and you're no longer considering them SLAs; therefore, you wouldn't be limited to 5 mW, and somebody could have a 5 W red laser to create the effect, so that's --

CAPT HEWETT: Right.

MR. ALDRICH: Okay.

DR. LOTZ: Let me go this way because we've been making them wait already.

Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

I also want to say I very much have been interested and impressed with the attention that the FDA is giving to these topics; I think they're all worthy topics. I am very supportive of the direction I'm hearing to build in engineering controls and that FDA is asking the hard questions and the important questions about standardizing with, for example, IEC. I think that the updates that were proposed to the laser standards were very careful, methodically put together, and am supportive of those, but for this afternoon's conversation, I want to just echo my concerns about adding to our standards here in the U.S. things from the IEC by reference to them as opposed to rephrasing and restating them, having our own single coherent publicly available document and instead refer, refer, go find this in the webpage.

I sat on those committees for too long and had too many times where they argued back to me, I don't care that that sentence isn't understandable to the common person, these documents are for manufacturers, been told that over and over. And we want something that enables the protection community, after it's gone to market, to continue to monitor the safe use, so the medical physicists, the radiation safety officers, we need clear, written language, and the type of things that we have in the federal regulations now, so I'm not -- I'm very concerned about seeing that go away.

Some of the other things that were brought up, I think we haven't had sufficient time and won't have sufficient time for discussion, but I think, again, they're good questions you're asking. The laser point is where I had my other -- laser pointers are where I had my other concerns, as have been echoed here. I think the "battery-operated" term in your definition is interesting and merits discussion. If you have a green laser pointer that is tethered electrically to a podium, is that acceptable, because you're not likely to drag the podium outside in the night to misbehave? So that "battery-operated" term caught my eye. But one of the questions specifically was do we think that these hazards, when they are misused, justify calling them defective, and I don't think so. I think that's a misappropriation of that term. The documents gave us what "defective" means. The blue and the green do help very much to accomplish their primary purpose, and so I don't think they are defective at all in having that. The risk of injury is the misuse of them, and that cat is out of the bag. Other countries will manufacture them; China may, as you say, drop-ship them. I think other solutions, technological, that could somehow intercept them, some sort of polarization, or I don't know the answer, it's not my expertise, but something in the windshields of planes is where the protection needs to come, not just trying to ban something that there are already too many of to keep out of the hands of people who do dumb things with them.

CAPT HEWETT: The windshield technology is actually in place. There's a firm that is doing that for some major airlines. It's extremely expensive.

DR. HOWARD: There's risks associated with that, also, because you're limiting the color vision of a pilot; they depend on being able to see red and green navigational aids.

CAPT HEWETT: Actually -- well, I think that's been solved.

DR. HOWARD: Okay.

CAPT HEWETT: But the -- I think the issue is, is market adoption. I mean, the biggest risk from laser pointers are the low-flying helicopters, the people who are medevacking people from one point to the next, and the military is dealing with it, especially the Coast Guard, with military flybys in coastal areas where resort towns are full of available green lasers. Kids just love to target rotary wing aircraft with those. And it's often characterized it's not just a matter of if, it's a when one of these products will contribute to a crash. We may never know; we may just have the crash so -- we have been, you know, the FBI has been very diligent, trying to go after laser illuminations at airports, and they have been unable to make a dent in the problem. LaGuardia, apparently, is a place that has come to the attention of Senator Schumer, where laser illumination of aircraft at critical takeoff and landing functions have spurred him to write us three times asking us to do something about it.

DR. McCOLLOUGH: Now, if push came to shove, would I rather have improved protection and safety for people in the air? Absolutely, rather than have my green laser pointer the next time I talk, especially since so many presentations have gone electronic and you can move your mouse around. So if that were the direction it went, I would actually be fine with that, though I think it is a bit of a feel-good step that we're doing something that may not actually reduce, just because there's so many out there.

And just I want to finish so I can yield my time and other's time to finish up. I don't think we had near enough time to discuss the near infrared. I think with the surveillance that benefits, that are so relevant in our society today, having photos of bombers from all these surveillance cameras, you know, the Boston Marathon and such, there's no doubt that our society is going to be peppered with these things, and so I'm glad to hear that you're working at it, and I think it does need effort and focus.

And my last comment is on the sunlamp discussion. It seems to be a big deal here. We had the most public comment on it. The speakers seem to have the expertise and be credible in their comments, and some of their concerns that some of the numbers may be arbitrary or, in fact, inhibit the value of what the product is supposed to be, I think need to be seriously considered, and so hopefully there could be some adjudication of what is being proposed to address those concerns, because I think those concerns, to my ears, sounded quite valid. And with that, I'll yield my time.

DR. LOTZ: Thank you, Dr. McCollough.

I believe Dr. Irwin is next.

DR. IRWIN: Yeah, thank you.

I find it ironic that of all the 22 questions here, 20 of them ask for opinions, and that's really mostly what we've got, and what I heard from the history of TEPRSSC actually, like the 2003 TEPRSSC resulted in a number of what seem to be decisions, and I'm frustrated that we're not likely to be able to reproduce that kind of productivity here. And that may be because of the questions, the way they're asked, and might be in the future that it's useful that you're able to winnow these questions down to something that could be almost voted upon by the body as opposed to providing all of us lots of opportunities to opine.

And that the one question that we have had the most debate on is the one that has the most closed question-ness nature to it, and that is about the green laser, and frankly, that's also what I wanted to opine about, and I would give an emphatic -- does the startle and flash blinding hazard with green and blue laser pointers justify calling them defective? In your presentation you said it presents a public health hazard, and I would agree. I believe that these lasers should be classified as defective. I don't really care that there's anybody that's using a green laser and getting a better emphasis with their slideshow. That makes no difference to me when the comparison is to an aircraft pilot suffering some sort of momentary or even longer debilitation that may put people at risk of a safe landing.

And so of all of these questions here, it's the only one that can be answered yes or no, and I would say yes. And I would also answer most of the other questions that are here, despite the limited time provided to discuss it here, and I think much more time is necessary, that I have been impressed by the research and the efforts of the FDA staff to present materials here and before we arrived here, to say that I support nearly all of the positions that FDA has made relative to these particular questions. It would be useful if it was possible to try to get to more specificity and see if there are ways that we might disagree with some of the specific stances that were to be taken as opposed to some of these opinions.

Thank you very much.

DR. LOTZ: Dr. Miller.

DR. MILLER: Donald Miller.

Just to clarify, you have me to blame. This is a non-voting meeting, and so I had all the questions phrased in a way that did not require a yes or no answer. Also, this way was intended to gather opinions from the number of individuals who represent a wide variety of knowledge and experience. So it's my fault.

DR. IRWIN: That's okay. I'm glad to actually have that clarification because I misunderstood the representation of, for example, the 2003 TEPRSSC, which seemed to have provided representation of really, boy, that was a dynamic group that really got a lot of strong perspectives related to FDA to work on for many years afterwards. And so as a follow-up, all of which you heard here today and we'll hear again tomorrow, is this being collected so that you will then act on it and provide some sort of feedback to us and the public as to what your reflection of that is and how you will then take steps in the future in a regulatory fashion?

DR. MILLER: Donald Miller.

And most certainly it's being collected, and we will be looking at all of it and considering it over the coming months. Our process of evaluation, consideration, and development is not public, but anything that we generate in terms of a proposed rule or a proposed guidance will certainly be public and will then be sent to the public for comment. And, of course, we look at the comments, as well, when they come back.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: Quick question because we're running out of time: If we have additional comments and so forth, is it useful to give it to you now? Is it like an intermediate period where you have a chance to influence perhaps what might come out in the future, or should we just wait for the public comment period because legally or whatever you have to not look at what we would say outside of this meeting?

DR. MILLER: Donald Miller.

I'm going to defer to Commander Anderson, but my understanding is that because this is a public meeting, we really have to have whatever is said, said in public. So something that you send to us afterwards in an e-mail or private conversation is not good.

MR. MURPHY: Even if it's sent as a private citizen or as a representative of whatever association? I mean, not saying I'm from TEPRSSC, but just, you know, I wanted to comment further on these. Does that help you or does that --

DR. MILLER: We always welcome advice and information from all sources.

MR. MURPHY: At all times?

DR. MILLER: At all times.

MR. MURPHY: Okay, great.

DR. MILLER: And we actually look at it as well.

(Laughter.)

DR. LOTZ: Dr. Linet.

DR. LINET: I would also like to compliment the staff for the huge amount of effort that they've put to summarizing things for this diverse group and trying to pinpoint the questions that they asked. I think from our viewpoint, we've talked about a lot of very common exposures, but the one that stands out is the one that's known to be associated with the most health effects, and that's UVR exposure, sunlamp exposure and tanning booths. So I think we need to keep into perspective -- I mean, I too, am sort of horrified at this idea of green lasers and blinding pilots, but I think in terms of the -- what we, in epidemiology, call the attributable risk to the population, which I think is very important, the exposures from sunlamps and tanning salons have been studied for a fair amount of time. I think the speakers from the public alluded to the large body of research. It is a growing body of research. I think we're still at the beginning from the point of epidemiology, but there's no question that the rates of melanoma and other skin cancers have been directly increasing, and there's a lot of data internationally, starting with our friends in Australia and friends in Europe and also the United States, that the rates of these particular outcomes, as well as potentially cataracts, have been increasing because of these devices.

So I think that when we think about focusing on what are the most important aspects, we ought to think about what is of the greatest public health importance and known serious outcomes that we have to deal with, and I think that's really where some of our attention needs to be focused, at least in today's session. We're going to get to some important stuff tomorrow, but I just wanted to make that point.

DR. LOTZ: Dr. Lambeth.

DR. LAMBETH: Thank you.

I just want to make a couple last comments, and please don't mistake my discussions about the laser pointer to mean that I think that the normal use of it is, you know, pointing at things should override all other considerations. I agree with Dr. McCollough. Basically, the cat is out of the bag, they're everywhere, and they will be continued to use even if we make a regulation; that's my feelings about that.

In that regard, I also wanted to comment because the question's here in front of me about protective housings, because we didn't really talk about how that would be done, and I just put it out to think about it a little bit because the virtual housing concept sounds nice, but in point of fact, if you -- if a child steps in front of one of these things and it's that bright, there's a very limited time to respond to shut it down. And I think that going forward, when you talk about virtual housing, you need to also think about the exposure time, not just the exposure, because most of these sensors that you would use, that are alternative to this process, take time to actually react, and it's not an insignificant amount of time, depending on how you choose to do this.

And that leads into the aspect of a LiDAR being the same way; is it scanning over a large area -- excuse me for being animated. But it's scanning over a large area, and you're asking is there something close in that field of view, and when I -- if I understand the near field or excuse me, the near infrared cameras and the projection, that virtual box goes out quite a ways, it's not close, and that means most other sensor technologies don't work because you don't get enough signal back; it means it takes more time. You can always trade signal for noise off for time, but you have to have solutions to these problems. So each one of these requires some thought before they're imposed on how the solution could occur, and probably that requires input from the industry who is building these things.

Thank you again.

DR. LOTZ: Go ahead, Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I have a question about the near infrared sensors. It is not clear, based on the fact that the Class IIIa limit for NIR is 0.1 mW compared to the IEC limits that are 30 to 40 mW, it's not clear why it should really be considered a potential harmful exposure. It may have to do with the size of the beam. If that is the case, I was wondering whether -- you know, an approach similar to classic radar theory where you minimize the probability of false alarm, and then you live with whatever probability of detection you can get, could, you know, be applicable in this case, where essentially by instituting rules that limit the power density, therefore the likelihood of injuries are very small value. And then, you know, living with the detection probability that is achievable after that goal is met could be a practical approach from your point of view. I really don't know all the details. Because I am -- you know, I'm a little bit skeptical about this, with no good knowledge or reason, okay, about this virtual protective housing, how could that work given -- the work that I do, environments, indoor/outdoor, and other factors that may influence the reliability of this virtual protective housing.

So I'm really wondering, if I think about long-range NIR detector, so everything that could be in between the detector location and the target, how is it possible to realize a very reliable virtual protective housing? I wonder if that's feasible. Actually, I wonder if you have examples of that. Maybe you do, and maybe that's why you put this on the table. So that was my thought about that.

DR. CALHOUN: Sure. William Calhoun.

So it depends a bit on the range, as you said. Long range, they have certain limitations. But there's also many instances of near infrared surveillance that are over, say, maybe just 100 m, not 2 or 3 km, and in which case they may require a different type of sensor to ensure a virtual protective housing that would be more appropriate for that distance. For long ranges, line-of-sight sensors using lasers can be used. They will function quickly and well at long ranges. They won't function quite as well, you know, closer to the detector, but through combinations of sensors, through geometric calculations, we've seen some solutions that seem to provide adequate safety. Does that answer your question?

DR. FARAONE: Yes, thank you.

CAPT HEWETT: I have a couple of examples, but can I mention a company name here in this, you guys?

(Off microphone response.)

CAPT HEWETT: No? Okay.

Well, we've seen technology where laser range finders have been used, and written variances that have approved the use of laser range finders that were very effective, and the feedback from the range finder either cut the beam out or lower the emission to a Class I level at that distance. And those are real markets that are -- I mean, real products that are out there right now.

DR. FARAONE: Thank you.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: I don't want to delay everyone, but I have a question about labeling. It seems like one of the very first things you would want to do to tell people who have a laser pointer is not to aim it at aircraft. So do you have any proposals for requiring, not just suggesting, but requiring a label on laser pointers to say do not point at aircraft?

CAPT HEWETT: Yeah, I think we -- you and I have discussed this in the past, you know; what's the practical limit of labeling on a laser pointer, and we already struggle with laser pointers not having the required labels just to designate class or manufacturer information. Adding another requirement, I don't know if that's going to be very practical considering that people -- you know, a lot of these illuminations are occurring from adults who know better --

MR. MURPHY: Sure.

CAPT HEWETT: -- who do it at night and are going to do it anyway. I don't know if they would necessarily pay attention to a label.

MR. MURPHY: I agree that they don't, but at the very first -- I mean, you know, one of the very first things hopefully that you do in safety is to tell people, is to give people a fighting chance to know that this is unsafe, to know that this is illegal, in a five-word statement, dangerous and illegal to aim at aircraft, something like that. It's like the warnings on cigarette packs. It's not going to stop people from smoking completely, but there will be people who pay attention to it, that when you go into a court of law and you say this guy shined a laser and look, it says on here it's illegal, so give them a higher sentence or a greater probability of being fined or jailed.

CAPT HEWETT: And certainly aircraft is just one problem. Motor vehicles have been targeted.

MR. MURPHY: Aircraft or vehicles, you have --

CAPT HEWETT: Marine vessels, I think recently we had a couple -- a ferry operator who crashed into another ferry because --

MR. MURPHY: But the -- overwhelmingly, it's aircraft. It's 20 times a night in the United States. I don't know if people know that. Twenty times a night in the United States reported to FAA, probably more that aren't reported, where a pilot sees lasers aimed at them. It's been about 40,000 times over the last 10 years in the U.S. and the UK. So it's very heavily done, and it's an intractable problem. I'm not saying that labeling is a solution, but since you already require some labels on there, and since you're having new regulations, I would respectfully suggest reconsidering that.

And also for some of these other products where we were talking about labeling, is somebody knowing that their microwave is hazardous or whatever, today with a QR code -- you know about, you know, my interest in this -- QR codes, a barcode, something that people can scan or a little tiny "Go to FDA.com/microwaves," and if they want to, if their microwave is acting up or whatever, they can find out safety information about it without having to track down the user manual; it's there permanently. If the technology changes, the safety information changes, you just change the website to reflect the updated information. So again, another suggestion.

CAPT HEWETT: Well noted, well noted.

Yeah, I just want to inform you guys that for laser pointer manufacturers, we currently suggest but we don't require a label that says laser light is bright and blinding at any distance; do not point at aircraft or other people, I think, something to that effect.

(Off microphone comment.)

CAPT HEWETT: It's too long, I know.

And I don't think anybody -- very many people have taken us up on that suggestion, but --

DR. LOTZ: Dr. Stein.

DR. STEIN: Toni Stein.

On the issue of labeling, to make sure that it's conspicuous. We haven't really talked about the UVA/UVC for nail salons and insect traps and the dangers and safety issues that you brought up in the materials to us. It just seems like a no-brainer to change the -- not to be able to interchange them in any way. For those that are lay people, do not understand the difference between UVC and UVA, it just should be, you know, an immediate change in a conspicuous way so that that can't happen.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: As I think about this intractable problem with the cat being out of the bag, what do you do when your farm is overrun with feral cats? You stop the production of cats; you get them all fixed. Sooner or later, if the manufacture of these is prohibited in the U.S., and other countries undoubtedly have people that do dumb things with these as well, I think that that is one way to address this intractable problem, is get a consensus of most countries and their authority, regulatory authorities and such, so we're not manufacturing them and there aren't as many people manufacturing them, and sooner or later, those of us that have a green laser, it will break or we'll forget we have it or --

UNIDENTIFIED SPEAKER: Wear out.

DR. McCOLLOUGH: It will wear out, whatever. So, in general, I don't think that the application of the "defective" word is the right quite angle; I think that's really a little trying to pinch, you know, put a square block in a round hole, but I am on board with the idea of stop the supply, if possible.

DR. LOTZ: Dr. Miller.

DR. MILLER: Just a side note, which I'm not sure that the Panel is familiar with. Defect has a very specific meaning in our regulations, and defect or a failure to comply to EPRC regulations gives us very specific authorities and powers amongst which are the ability to require the manufacturer to repair, replace, or repurchase a defective device, defective product. Whether that would be practicable, effective, or even possible in the situation of laser pointers, I don't know, but it is an authority that we have under existing regulations for a defective product.

CAPT HEWETT: Yeah. And I might add that it also has a very significant meaning in terms of our import regulations allowing us to take certain actions.

DR. McCOLLOUGH: So you're purposely trying to use that word --

CAPT HEWETT: Yes.

DR. McCOLLOUGH: -- because it gives you more authority?

CAPT HEWETT: That's correct.

DR. McCOLLOUGH: Understood.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

Kudos also to you folks for putting together such a nicely presented set of documents for us to review. Took a lot of effort and work on your part, and obviously you're very concerned about all the situations you're addressing; you've taken it to heart, and I appreciate that. When I saw the word "defective," it brought me back to thinking about the mafia and how tax evasion took them down, and realize that classifying something as defective provided a great regulatory strength for FDA, so I can understand that. I was initially thinking this is just your way around regulation, but it is your way of using regulation effectively to control a market. So yes, I can understand that.

Like Dr. McCollough, I was thinking about aircraft windows and how to protect them, and obviously it's a very expensive proposition, but it can be done. Got into thinking about the battery-powered lasers, and like Dr. McCollough, I was thinking, well, you have 120 V power, you have tethering, you can hook them up to your laptop, and chances are as solar improves, you'd be able to make them solar-powered, so limiting your definition to battery power may be problematic in the future for FDA to regulate because you find examples of non-battery-powered units and without any regulatory control. So I would encourage you to think about how to provide some weasel words or any other way to define them that precludes you from having to use only battery-powered for their operation.

CAPT HEWETT: You know, we did take that into consideration. The alternative would be an electrical main, which could tether you to an outlet, and we felt like that sufficiently limited the portability of the product. What you're looking at is really a handheld, battery-powered, portable laser source, and we felt like --

MR. KEITH: Well, perhaps just the word "portable" would suffice rather than having the word "battery" in there.

CAPT HEWETT: It's hard to define portability in a regulatory sense, but we could try. But your points are well taken.

MR. KEITH: And I was also looking at the dark-adapted and light-adapted response to laser radiation, and my first thought was just label it not for nighttime use seemed like it's protective enough if it's during daylight hours but potentially a lot more problematic if it was used after hours, and also I think perhaps the wavelength can be tweaked a bit because I think there was indication that less than 430 was probably okay, especially you look at the graph. And I don't know, I think there's some lasers that operate below 430 rather than just below 410 that you may want to consider when trying to limit the frequency of the particular lasers.

And going on to the tanning booths, you know, it was -- I guess noncoherent light source and all, about the circadian rhythm that's altered, and that seems to be a significant health endpoint that FDA can point to, to say, you know, if a circadian rhythm can be altered, then perhaps regulation needs to be brought to bear to ensure that the effects are minimized. And then I found Tosini et al. 2016 on effects of blue light on the circadian system in eye physiology, and they pointed out there that blue lasers are used to treat rather than cause circadian rhythm and sleep dysfunctions. So it looks like there's a dual use of blue lasers, so I'm not sure to what extent one overpowers the other, but at least we should probably take a look at what the current literature says about the positive as well as the negative aspects on health of use of these laser products.

And also, I still wonder if there might be a cumulative effect and would encourage FDA not to discount the possibility that just maintaining doses below, exposures below a threshold might be sufficient. But I would encourage the thought of even the -- of ALARA concept. Sometimes it's better to be safer in the short term rather than be recognizing it as a problem long term. Nothing hurts to say, you know, these are the limits, but efforts to reduce exposure below that may be useful for public health protection purposes.

Thank you very much.

DR. LOTZ: I want to thank the FDA staff for all of their efforts. Second, all my colleagues on the Panel have already spoken; clearly, a great deal of work has gone into this, and there's many topics of great significance here. I want to thank my colleagues on the Panel for a long day. We have much to do tomorrow as well.

I want to turn to Dr. Miller and ask you if you have any final remarks you'd like to make today to the Panel.

DR. MILLER: Other than to thank the Panel and the public speakers and the FDA presenters for all of their efforts today, no. There will be somewhat more time for the committee deliberations tomorrow than there was today, and if you wish to bring up any of the topics discussed today and revisit them tomorrow, that's your option as well, so -- but thank you.

DR. LOTZ: That's good to keep in mind because we clearly, I think, as Mr. Murphy summarized best, had more questions than we had time to answer today. So yes.

So let me turn to Commander Anderson for some final remarks.

CDR ANDERSON: Yes, for panelists, could you please hold on to your gray folders and bring them back tomorrow because they do have copies of the slides for tomorrow, so thank you.

DR. LOTZ: And with that, I will pronounce Day 1 of our TEPRSSC meeting to be adjourned, and we'll reconvene again at 8:30 tomorrow morning.

(Whereupon, at 5:48 p.m., the meeting was continued, to resume the next day, Wednesday, October 26, 2016, at 8:30 a.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

October 25, 2016

Gaithersburg, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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